A comparison in the clinical application, patient experience and costs between independent nurse prescribing and patient group directions in sexual health services.

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A comparison in the clinical application, patient experience and costs between independent nurse prescribing and patient group directions in sexual health services

By

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Abstract

INTRODUCTION:
Nurses legally deliver medication through independent nurse prescribing (INP) or patient group directions (PGDs). There is limited sexual health evidence of clinical application and patient experience.

METHODS:
Multiple mixed methods design was used in this study involving: staff interviews and questionnaires, clinical diary, clinical notes review, consultation observations, patient questionnaires and a costs review in five UK sexual health services, between September 2015 and August 2016.

RESULTS:
Staff interviews reported governance and service delivery preferences for INP over PGDs, but they valued both methods.
Staff questionnaire response rate: 64% (61/95; INP=26/28, 93%; PGD=35/67, 52%). INP were mainly Band 7 (n=13/26, 50%), educated to Masters (n=16/26, 62%); PGD users were mostly Band 6 (n=24/35, 68.6%), educated to Diploma (n=13/35, 37%). Both groups reported that medication access made their roles easier (n=60/61, 98%).
Clinical diary: There was no difference in medication delivery frequency between both groups (INP=460/737 care episodes, 62%; PGD=348/593, 59%; p=0.168); however, PGD users required more professional support for medication delivery compared to INPs (INP=419/460 care episodes, 91%; PGD=245/348, 70%; p<0.001).
Notes review: INPs delivered medication more frequently (INP=385/711 care episodes, 54%; PGD=548/1,140, 48%; p=0.011) and worked more autonomously than PGD users (INP=310/399 medication delivery care episodes, 78%; PGD=308/480, 64%, p<0.001). Overall, 91% (n=798/879) of medication delivery episodes were assessed against guidelines as 'safe and appropriate' (INP=372/399, 93%; PGD=426/480, 89%). The main reason for not being 'safe and appropriate' was lack of documentation (n=56/104, 54%). PGDs were used outside their restrictions in 8% (n=39/480) of consultations.
Patient questionnaires: 92% response rate (n=360/393). Patients reported a high degree of satisfaction with information about medication (Satisfaction with Information about Medicines Scores: 13.4/16: the higher the score the greater the satisfaction).
Observational study: nurses medication delivery consultations scored very highly against the prescribing framework (INP=44.7/46; PGD=45.4/46, p=0.407).
Costs: INP training and governance required more initial investment, compared to PGDs, but facilitated INPs to autonomously manage more clinically complex patient presentations.

DISCUSSION:
INPs and PGDs support safe autonomous practice. INP offered a highly flexible method of medication delivery that facilitated management of complex patient presentations but requires extensive resources from the NHS, and individual nurses, which were not always readily available. PGDs offer a suitable alternative, but were sometimes used outside of their restrictions. Improved clinical documentation is recommended throughout.

CONCLUSION:
Independent access to medication using INP and PGDs has facilitated a paradigm shift for nurses, progressing them from doctors' handmaidens to autonomous advanced clinical practitioners. Access to medication is now a fundamental component of the advanced sexual health nursing role.

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Abbreviations

Abbreviation	Meaning
AEI	Approved Education Institution
AU	Action & Usage (part of SIMS)
BASHH	British Association of Sexual Health & HIV
BME	Black & Minority Ethnic
BNF	British National Formulary
BV	Bacterial Vaginosis
CASP	Critical Appraisal Skills Programme
CCA	Costs & Consequences Analysis
CCG	Clinical Commissioning Groups
COCP	Combined Oral Contraception Pill
CRN	Clinical Research Network
CSP	Co-ordinated System for gaining NHS Permission
df	degrees of freedom
DFSRH	Diploma for Faculty of Sexual & Reproductive Health
DH	Department of Health
DHSSPSNI	Department of Health, Social Services and Public Safety Northern Ireland
DMP	Designated Medical Practitioner
DOB	Date Of Birth
EC	European Community
EEC	European Economic Community
EU	European Union
FPA	Family Planning Association
FSRH	Faculty of Sexual & Reproductive Health
GCP	Good Clinical Practice
GDPR	General Data Protection Regulation
GP	General Practitioner
GSL	General Sales List medication
GUM	Genitourinary medicine
HEE	Health Education England
HEI	Higher Education Institute
HIV	Human Immunodeficiency Virus
HRA	Health Research Authority
HSCIC	Health & Social Care Information Centre
INP	Independent Nurse Prescribing/ Prescriber(s)
INP med	Medication episodes primarily managed by INP
INP no med	Medication NOT provided in episodes managed by INP
IT	Information Technology
IUD/ IUS	Intra-Uterine Device/ Intra Uterine System
KCL	King's College London
LA	Local Authorities
MAI	Medication Appropriateness Index
MedFASH	Medical Foundation for HIV & Sexual Health
MHRA	Medicines and Healthcare products Regulatory Agency
MSM	Men who have Sex with Men
NAAT	Nucleic Acid Amplification Test
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
NIHR	National Institute for Health Research

Abbreviation	Meaning
NMC	Nursing & Midwifery Council
NPC	National Prescribing Centre
NPSA	National Patient Safety Agency
NSU	Non-Specific Urethritis
P	Pharmacy sales medication
P.	Participant
PCF	Prescribing Competency Framework
PCT	Primary Care Trust
PEP/SE	Post Exposure Prophylaxis (/Sexual Exposure)
PGD	Patient Group Direction
PGD med	Medication episodes primarily managed by PGD
PGD no med	Medication NOT provided in episodes managed by PGD
PHE	Public Health England
PID	Pelvic Inflammatory Disease
PIS	Participant Information Sheet
PMH	Past Medical History
POM	Prescription Only Medication
PPI	Patient Public Involvement
PPM	Potential Problems of Medication (part of SIMS)
PSD	Patient Specific Direction
R&D	Research & Development
REC	Research Ethics Committee
RPS	Royal Pharmaceutical Society
SI	Statutory Instrument
SIMS	Satisfaction with Information about Medications Scale
SPSS	Statistical Package for Social Sciences
SRH	Sexual & Reproductive Health
STI	Sexually Transmitted Infection(s)
STIF	Sexually Transmitted Infection Foundation
TOP	Termination Of Pregnancy
TTO	To Take Out
TV	*Trichomonas vaginalis*
UK	United Kingdom
UKMEC	UK Medical Eligibility Criteria (for contraception provision)
WHO	World Health Organisation
χ^2	Chi-squared test
t	Independent Samples t Test
Rx	Prescription

Preface: Overview

Research Context

Appropriately trained nurses in the United Kingdom (UK) are able to independently deliver medication through patient group directions (PGDs) and independent nurse prescribing (INP). PGDs allow groups of locally competent nurses to supply/ administer specific medications from a range of pre-determined clinical presentations. Conversely, INP affords individual nurses prescribing powers comparable to doctors following successful completion of a Nursing & Midwifery Council (NMC) approved training course. Over the last 13 years there has been an 853% (n=35,407) increase in NMC registered 'Nurse Independent / Supplementary Prescribers'; rising from 4,151 in 2005 to 39,558 in 2018 (NMC, 2005; NMC Freedom of Information, 2018). Due to the episodic nature of sexual health patient presentations, both INP and PGDs have been found to be clinically effective in this speciality (Miles et al., 2001; Black, 2012). Of note, PGD use is not 'prescribing', rather they facilitate nurses' independent supply and/ or administration of medication. Consequently, throughout this thesis the term 'medication delivery' is used to denote both PGD users and INPs' independent provision of medications.

Any form of medication delivery is a complex process that involves multiple considerations to achieve desired pharmacological effects in a safe, cost effective and patient focussed way. Prescriptions were the second highest cost to the National Health Service (NHS) (after staffing: Health & Social Care Information Centre (HSCIC), 2014) costing £17.4 billion in England in 2016-17 (NHS Digital, 2017). As well as being one of the most expensive outlays, medicine provision is also one of the most hazardous (Leufer and Cleary-Holdforth, 2013). Medication errors were the third highest patient safety incidents reported, after accidents and implementation of care/ monitoring issues (NHS Improvement, 2017). The most common medication incidents included wrong dose, omitted or delayed drugs and wrong medication supplied (National Patient Safety Agency (NPSA), 2012).

Despite the exponential growth of nurses delivering medication, there is limited evidence available that has specifically explored safety and cost effectiveness of medicines delivery by nurses. This health services research study explored nurse delivery of medication within the context of sexual

health, an area in which nurses' roles have become increasingly autonomous as a result of increased service demand (NHS, 2013).

Research aim and objectives

The study's aim was to explore how sexual health nurses' use of independent nurse prescribing compared with the use of patient group directions in terms of clinical application, patients' experience and cost.

The study's objectives were to:

1. Determine the extent to which sexual health nurses' professional experience and scope of practice affect prescribing practice or PGD use.

2. Explore INP practice and the use of PGDs by nurses working in sexual health services; investigating frequency, range, appropriateness, safety and outcomes of medicines delivery.

3. Assess whether and how local application of INP and/ or PGDs has benefited patients, health professionals and the NHS, with reference to quality of care, appropriate management of sexual health care episodes, and value for money.

Overview of research design

A multiple mixed methods approach was adopted with data collected concurrently and simultaneously across three inter-related work streams. These work-streams explored INP vs. PGDs in sexual health within the context of:

- Clinical application:
    - Impact on professional practice and service delivery
    - Safety and appropriateness of medication delivery
- Patients' experience and satisfaction with information about medicines
- Costs comparison of INP vs. PGDs using a costs & consequences analysis

The methods involved NHS senior staff interviews, INP and PGD staff questionnaires, quantitative clinical diaries, clinical notes review, an observational study, patient experience questionnaires and an economic evaluation. These methods were based on a Department of Health (DH) commissioned study, carried out by Latter *et al.* (2005), which subsequently supported the expansion of INPs' prescribing powers (DH, 2006). Five city-based UK sexual health services participated, three located in England, one in Scotland and one in Wales.

Thesis structure

This thesis comprises of six chapters. The first chapter presents INP and PGD legislation and a general overview of the literature relating to nurses' medication delivery. Chapter two discusses sexual health as a clinical speciality, healthcare governance within the field, sexually transmitted infection (STI) demographics and modernisation of the sexual health nursing role. Chapter three presents empirical research specifically related to safety and appropriateness of INP/PGDs, patients' experience of nurses' medication delivery, and a cost comparison between INP vs. PGDs.

The multiple mixed methods study design added a layer of complexity on how best to present the methods and findings. For ease of reference, chapter four provides a general overview of the study's overarching methods, detailing justification for the chosen approach, data collection and research governance considerations. Chapter five then presents each task's specific methods

alongside their findings, starting with ‘staff interviews: task specific methods’, followed by ‘staff interviews: findings’. The staff questionnaires, clinical diary, clinical notes review, clinical observations, patient experience questionnaire and costs then follow a similar structure. The sixth chapter initially presents this project’s contribution to knowledge, before discussing how INP vs. PGDs compared through triangulation of the various methods’ findings around the study’s objectives. The thesis concludes by highlighting the study’s limitations, impact for clinical practice, recommendations for future research and an overall conclusion.

CHAPTER 1: **BACKGROUND**

1.1 Introduction

This project explored nurses' delivery of medication from a clinical application, patient experience and cost perspective in sexual health. Sexual health was specifically chosen due to the researcher's extensive clinical experience in this field. Moreover, the researcher's clinical, professional and academic interest lay in ensuring nurses provided safe, patient focussed, cost effective care. This chapter presents the legislation relevant to nurses' delivery of medication, specifically focussing upon comparing INP vs. PGDs, as these two methods are frequently used in sexual health (Black, 2012). A general overview of literature relating to nurses' medication delivery internationally and UK-based is then presented.

1.2 Nurse medication delivery legislation background

The UK's medication legislation is governed from a variety of sources (Woodley, 2009), which is likely to be amended following the UK's vote to leave the European Union (UK Government, 2018a). However, during this study the European Community (EC) had certain Regulations and Directives that took precedence over UK law. UK based legislature could then govern the entire UK or be unique to the devolved parliaments of England, Scotland, Wales and Northern Ireland (Woodley, 2009) through country specific government health departments, as detailed in Table 1-1.

Table 1-1 Government healthcare departments across the United Kingdom

Country	Healthcare Department
England	Department of Health & Social Care (DH: Previously Department of Health)
Scotland	Scottish Government Health and Social Care Directorate
Wales	Welsh Government Department for Health & Social Services
Northern Ireland	Department of Health (Northern Ireland) (previously Department of Health, Social Services and Public Safety (DHSSPSNI))

(DH, 2018b; Department of Health in Northern Ireland, 2018; Scottish Government, 2018; Welsh Government 2018).

The '*Medicines Act 1968*' constituted the UK's introduction of medicines regulation. Medicines were categorised as 'Prescription Only Medication' (POM) which could only be prescribed by a doctor, dentist or vet; 'Pharmacy' medicines (P) which could be provided by pharmacists; or a 'General Sales List' (GSL) which could be generally supplied (*Medicines Act, 1968*, c.67). Nurses' independent access to medication was first introduced following 'The Cumberledge Report' (1986). This allowed community-based nurses to access commonly used dressings and medications, avoiding the need to obtain general practitioner's (GP) prescription. Subsequent legislation expansions are summarised in Figure 1-1. Most significant for nurses was the introduction of PGDs in 2000 (Department of Health (DH), 2000), and in 2006 the substantial legislation amendment giving INPs the authority to prescribe any licensed medication (and some controlled drugs) within their competence (DH, 2006; NMC, 2006). Scotland and Wales have both incorporated non-medical prescribing legislation based on England's DH authorisations and updates (Home Office, 2012). Northern Ireland incorporated non-medical prescribing using their own legislative process, sanctioning it seven months after the rest of the UK, in December 2006 (DHSSPSNI, 2006). Nurse and pharmacy independent prescribers were afforded similar prescribing powers as doctors. Patient safety, improvements in service delivery and better use of professional's skills were the key drivers (DH, 2006). These acts have since been superseded with '*The Human Medicines Regulations* 2012' (SI 2012/1916). This study focused on PGDs and INPs application within sexual health nursing.

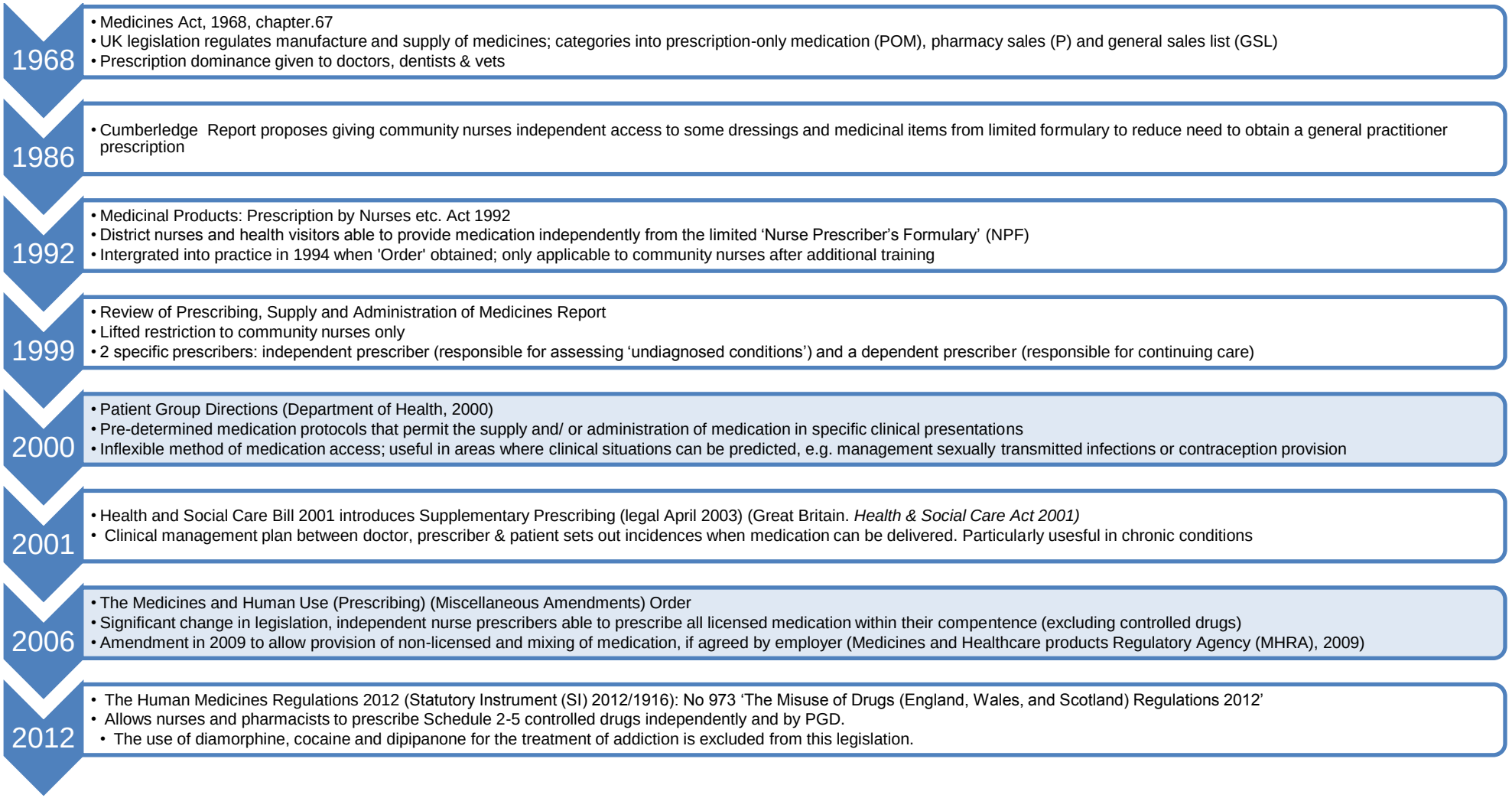


Figure 1-1 The evolution of independent nurse access to medication

1.2.1 Patient group directions

PGDs are pre-determined medication protocols, which were introduced in 2000 to improve access to medications (DH, 2000). PGDs must be signed by a doctor and agreed by a pharmacist and the lead professional of the team(s) using them. PGDs authorise groups of registered healthcare practitioners to independently supply and/ or administer specific medications in pre-defined circumstances (using their own assessment of patient need), without referring to a doctor for a prescription. Supply or administering medication using a PGD is not prescribing. Unlike prescribing patients do not need to be individually identified prior to PGD use, however their presentation must meet the pre-set criteria for legal supply and/ or administration of the medication. PGDs offer no flexibility; if the PGD does not cover the patient's presentation, a prescription from a qualified prescriber is required. PGDs are extremely useful in clinical areas where treatment patterns and patient presentations are predictable; e.g. management of sexual infections or contraception. PGDs have the benefit of facilitating entire teams of registered practitioners to independently deliver medication without the need for additional Higher Education Institute (HEI) qualifications (The National Institute for Health and Care Excellence (NICE), 2013). PGDs' legal content is presented in Box 1.1. Legally, PGDs must be reviewed every 3 years and can include all licensed POM and some controlled drugs. They cannot, however, contain unlicensed medications. The person supplying or administering the medication using a PGD cannot 'delegate' another professional to supply, dispense or administer the medication (NICE, 2013).

Box 1.1 PGD legal content

- Dates they are valid (from – to)
- Name of medicine and the eligible condition(s) that can be treated using this medication
- Exclusion criteria, limitations of use and when the patient should be referred/ discussed with another healthcare professional
- Pharmaceutical form(s), strength, dose, route, frequency of administration of medicines and the minimum/ maximum times the medicine can be supplied/ administered
- Relevant warnings, follow-up instructions and arrangements for medical advice
- How the provision of medication via a PGD will be recorded (*The Human Medicines Regulations 2012*, Schedule 16, p.230)

1.2.2 Independent nurse prescribing

The NMC, who regulate all UK registered nurses and their prescribing powers, specify nurses must always be aware of their professional, clinical, legal, accountable and ethical positions as nurses and prescribers (NMC, 2006; NMC, 2015). To become an INP, candidates must be a registered first level nurse, with a minimum of 3 years post-registration experience; the preceding year in the clinical area in which prescribing is likely to occur. Candidates should be able to undertake clinical assessments, make diagnoses, consider treatment options and create care management plans. Upon successful completion of the INP course, registration with the NMC and authorisation from the prescribers' employer must be obtained before nurses can commence prescribing (DH, 2006; NMC, 2006). Only an NMC Approved Education Institution (AEI) can provide prescribing training. The programme is a combination of 12 clinical training days and 26 theoretical days (minimum) delivered at degree level or higher. Designated Medical Practitioners (DMPs) are required to supervise and mentor students through the 12 clinical training days (DH, 2006). Evidence suggests one third of prescribing students spend the full allocated time with their DMP, while others rely upon other professional colleagues; including pharmacists, nurses and other doctors (Latter et al., 2007c). While most students are satisfied with their DMP, some also report their DMPs have a lack of time for the role or inadequate teaching skills (Latter et al 2007c; Ahuja, 2009; Smith et al., 2014).

1.3 INP versus PGDs

INP and PGDs both have advantages and disadvantages, summarised in Table 1-2. The key differences are that PGDs can be used by large groups of clinical staff through internal competency training, however they are extremely restrictive in application and require extensive stakeholder effort to create, govern and maintain them (NICE, 2013). By contrast, INP is extremely flexible but can only be used by individual nurses who have undertaken appropriate AEI training (NMC, 2015). Both INP and PGDs have resource implications which require additional investigation, particularly on costs versus returns for the NHS. Two papers (Brookes & Smith, 2007; Wat et al., 2014) argue PGD benefits outweighed INPs, particularly as PGDs do not require individual nurses to undertake expensive and time-consuming prescribing courses. However, these studies do not consider the

complex PGD governance processes, or that PGDs are not always used appropriately in practice (Deave et al., 2003; Black, 2012). That being said, should an INP leave employment the investment in that nurse is also lost; therefore, PGDs offer suitable resilience should staff leave. Nevertheless, university-based training mean that INPs benefit from rigorous, regulated, standardised training which provide university credits towards Degree or Masters pathways (NMC, 2006). Similar standards of training or academic pathways are not available for PGD training (Bradley and Nolan, 2007). Both INP and PGDs are widely reported to benefit clinical practice in various clinical areas (Miles et al., 2001; Brooks et al., 2003; Deave et al., 2003; Balieff, 2007; Latter et al., 2007a; Stenner and Courtenay, 2008; Courtenay et al., 2009a, Courtenay et al., 2009b; Courtenay et al., 2010; Jones et al., 2010; Courtenay et al., 2011; Price et al., 2012; Black and Dawood, 2013; Wilkinson et al., 2013; Carey et al., 2014; Creedon et al., 2015; Ross, 2015).

Table 1-2 Summary of INP and PGD governance requirements

Requirements of use	INP	PGD
Local Trust permission	✓	✓
Professional registration & accountability	✓	✓
Additional registration	✓	✗
University education	✓	✗
Flexibility	Within competence	None
Range of use	Individual nurses	Individuals/ groups deemed locally competent

INP= independent nurse prescribing, PGD= patient group directions

1.4 Nurse delivery of medications internationally

Nurses are able to independently prescribe in a variety of countries including Australia, Canada, Ireland, Spain, New Zealand, Norway, South Africa, Sweden, the Netherlands, UK, United States of America (Kroezen et al., 2011; Gielen et al., 2014), Israel and Poland, and other countries are considering doing so (e.g. China (Ling et al., 2018)). Australia, Canada and the UK also use PGDs/ medical directives. The number of countries adopting nurse prescribing has grown considerably within

the last two decades (Kroezen et al., 2014c). However, the actual freedom to prescribe varies considerably between countries; consequently the term 'independent nurse prescriber' does not have the same definition globally. Internationally this can refer to a limited formulary of specific medications or a wider freedom to prescribe (Gielen et al., 2014). The legal, educational and stakeholder conditions heavily influences how nurse prescribing can be integrated into service delivery (Kroezen et al., 2011). Research that has reviewed the success of nurse prescribing is limited nationally and internationally (Gielen et al., 2014). This study, therefore, focussed predominantly on UK literature to support relevant comparisons with UK legislation and clinical practice.

1.5 Overview of medication delivery by nurses in the United Kingdom

Existing UK literature identified INPs are predominantly based in primary care services (Courtenay, Carey & Burke, 2007a; Latter et al., 2007c; Courtenay & Carey, 2008; Courtenay & Gordon, 2009; Bhanbhro et al., 2011; Carey et al., 2013; Drennan et al., 2014) but the benefits of independent medication delivery are increasingly becoming recognised in a range of secondary care settings (Jones, 2009; Cole & Gillet, 2015). It is evident that the job titles of nurse prescribers vary and include: nurse practitioners, practice nurses, team leaders and nurse specialists, and the majority of INPs significantly exceed the NMC's three year minimum qualified experience, and nurses have academic achievements of degree level or higher (Courtenay, et al., 2007a; Latter et al., 2007c; Courtenay and Carey, 2008; Courtenay et al., 2012; Boreham et al., 2013; Smith et al., 2014). Sexual health and emergency contraception prescribing are frequently undertaken in primary care (Courtenay & Gordon, 2008; Drennan et al., 2014), and medications are delivered for approximately every second patient episode in sexual health and emergency departments (Black, 2012).

A range of organisational, clinical, professional, and patient benefits of nurses' delivering medications have been identified. These benefits primarily focus on improved medication access and patient experience (Courtenay et al., 2009a; Courtenay et al., 2009b, Courtenay et al., 2011; Drennan et al., 2011; Stenner et al., 2011; Bergman et al., 2013; Tinelli et AL., 2013). Studies reported that being responsive to patients' clinical and medication needs facilitated better disease control and symptom management (Latter and Courtenay, 2004; Bradley and Nolan, 2007; Stenner and Courtenay, 2008;

Wilkinson et al. 2013; Carey et al, 2014). Improved safety associated with medicines management have also been found as nurses take responsibility and accountability for their own medication decisions (Bradley et al., 2005; Bradley et al., 2007; Bradley and Nolan, 2007; Pontin and Jones, 2007; Stenner and Courtenay, 2008; Courtenay et al., 2009b; Price et al. 2012; Schirle & McCabe, 2016), although some studies have identified medication delivery errors by nurses (Carey et al., 2008; Dornan et al., 2009; Bates et al., 2010; Avery et al., 2012; Seden et al., 2013). Therefore, safety of medicines management needs to remain at the forefront of practitioners' practice. Improvements in communication and therapeutic relationships have also been frequently reported (Latter and Courtenay, 2004; Bradley et al., 2005; Pontin and Jones, 2007; McCann et al., 2008; Hobson et al., 2010; Norman et al., 2010; Dhalivall, 2011; Drennan et al., 2011; Stenner et al., 2011; Wilkinson et al., 2013; Ross et al., 2013; Ross 2015), as has closer working relationships between doctors and nurses (Avery et al., 2007; Bradley and Nolan, 2007; Earle et al., 2011; Bowskill et al., 2013; Ross, 2015). Nurses' independent delivery of medication has been identified as having the potential to improve medication adherence, patient involvement, and quality of consultations (Latter et al., 2007d; Drennan et al., 2011; Banicek, 2012). From an organisational perspective, implementing nurses' medication delivery has made better use of the workforces' skills through autonomous practice, which has facilitated a more comprehensive and efficient service delivery (Bradley et al., 2005; Bradley and Nolan, 2007; Pontin and Jones, 2007; Stenner and Courtenay, 2008; Courtenay et al., 2009b; Black, 2012; Naughton et al., 2012; Wilkinson et al., 2013; Carey et al., 2014; Creedon et al. 2015). Nurses also report that the ability to deliver medicines has improved job satisfaction, self-esteem and confidence (Courtenay et al, 2007a; Pontin and Jones, 2007; Stenner and Courtenay, 2008; Jones et al, 2010; Gumber and Gajebasia, 2012; Carey et al., 2014; Creedon et al., 2015). Moreover, medical staff report that the ability of nurses to deliver medicines enables them to focus on more complicated clinical presentations (Earle et al., 2007; McCann et al., 2008; Berry et al., 2008; Courtenay et al., 2010; Banicek, 2012, Mac Lure et al., 2013). Medicines delivery by nurses has also been reported to facilitate flexible working, saving time for patients as a result of involving fewer healthcare professionals across their consultation appointments (Jones et al., 2010; Courtenay et al., 2011; Drennan et al., 2011; Earle et al., 2011; Ross, 2015). Furthermore, the time spent with patients has been reported by nurses as more beneficial, as they are able to focus upon answering patient

questions and information provision concerning medication regimens, as opposed to obtaining prescriptions from doctors (Bradley and Nolan, 2007; Drennan et al., 2011, Stenner et al., 2011), and patients positively valued these interactions with nurses (Latter et al., 2007d; Drennan et al., 2011).

Barriers related to nurses' medication delivery have been reported, these barriers primarily associated with logistics and medication governance (e.g. difficulties in accessing prescribing stationary, budgets or electronic systems). In some areas, doctors and pharmacists have been reported to be reluctant to allow nurses to deliver medicines (Bradely and Nolan, 2007; Courtenay et al., 2007a), while conversely, other nurses have reported being sent on the prescribing course rather than volunteering (Bradley et al., 2005). This has created concern over additional burdens to already heavy workloads, and a shift from foundational nursing care to advanced practice roles (Bradley and Nolan, 2007). However, many trusts now include nurse prescribing within job descriptions and contracts, suggesting medication delivery had become an expectation for nurse practitioner roles (Smith et al., 2014). Moreover, a small minority of nurses have reported that they do not feel fully prepared for delivering medications following training (Latter et al., 2007c; Smith et al., 2014). Indeed Bradley and Nolan (2007) identified that completion of training was seen as the start of the process, rather than equipping nurses with lifelong medication knowledge and skills. Confidence was seen to grow with experience (Bradley and Nolan, 2007; Cashin et al., 2014). A lack of continuing professional development (CPD) opportunities, peer support, and confidence in prescribing skills has also been reported (Courtenay et al., 2007b; Latter et al., 2007c; Green et al., 2008; Courtenay and Gordon, 2009; Creedon, 2010; Gumber and Gajebasia, 2012; Creedon et al., 2015). However, the main barrier to INP is the prescribing programme, and the need to undertake much of this in nurses' personal time, frequently without recompense (Earle et al., 2011; Boreham et al., 2013).

1.6 Background summary

The expansion of UK legislation has facilitated nurses to deliver medications independently through INP and PGDs. Benefits and barriers for both methods have been demonstrated throughout this chapter. INP is a flexible method of medication delivery, however, is limited to individual nurses who have successfully completed an expensive labour-intensive university course. By contrast, PGDs can

be used by entire teams of practitioners following local training, yet are extremely restrictive in clinical practice, and require a large amount of local governance. Nevertheless, the integration of INP and PGDs has supported organisational, clinical, professional and patient benefits across a wide range of clinical specialities. However, the potential for medication errors and barriers to delivering medication have been reported. The nature of sexual health means that INP and PGDs are both appropriate mechanisms by which sexual health nurses are able to deliver medications independently. The next chapter presents an overview of sexual health and the nurses' role within this speciality.

CHAPTER 2: **SEXUAL HEALTH AND NURSING**

2.0 Introduction

This chapter presents sexual health as a clinical speciality, how it is governed/ influenced, STI demographics, and the modernisation of the sexual health nurses' role.

2.1 Sexual health as a clinical specialty

Sexual health is defined as "*a state of physical, emotional, mental and social well-being in relation to sexuality; it is not merely the absence of disease, dysfunction or infirmity. Sexual health requires a positive and respectful approach to sexuality and sexual relationships, as well as the possibility of having pleasurable and safe sexual experiences, free of coercion, discrimination and violence. For sexual health to be attained and maintained, the sexual rights of all persons must be respected, protected and fulfilled*" (WHO, 2006). The concept of being sexually healthy therefore goes beyond being free from sexual infections, but incorporates a holistic approach of contentment, freedom and wellbeing. Individuals, communities and cultures all have different perceptions and experiences of what constitutes good sexual health. Consequently healthcare strategies must be sympathetic to the requirements and influences affecting sexual expression and choice in the populations they serve. This permeates to all healthcare fields as sexual health can be affected by other medical and psychological conditions or treatments (Evans, 2013).

Sexual health specific services in the UK aim to support and promote healthy sexual lives. Delivery of these services has historically been through distinct specialities: Sexual & Reproductive Health (SRH); Genitourinary Medicine (GUM) and Psychosexual. These services are now moving to an integrated approach providing contraception; STI screening, management and prevention; termination of pregnancy services; and health and relationship promotion (DH, 2013). The benefits of offering integrated services aims to improve access to services and ultimately improve public health.

2.2 Sexual Health Legislation and Governance

There are a number of factors that govern and support the complex array of sexual health services. Services in the UK are mostly open-access, delivered free to the user and include the provision of medication with no prescription charges, regardless of the patients' country of origin (DH, 2013). Users' identity and confidentiality (with regards to STI screening, diagnosis and treatment) is protected through the '*NHS (Venereal Diseases) Regulations 1974*', and the '*Health and Social Care (Safety and Quality) Act 2015*'. This legislation restricts an individual's information being shared unless it is for treating or preventing the spread of an STI. Delivering free, open access and confidential services to individuals aims to improve sexual health on a public health level. Confidentiality under existing legislation does, however, have limitations, particularly where abuse is evident or suspected, or other vulnerabilities are exposed (e.g. sexual exploitation, child abuse, domestic violence, sexual assault, safeguarding issues, female genital mutilation). This is particularly relevant when managing children, young people or vulnerable adults (*Family Law Reform Act 1969*, c.46; *Sexual Offences Act 2003*, c.42; British Association for Sexual Health & HIV (BASHH), 2010; BASHH 2011, Care Quality Commission (CQC), 2014).

Policies and frameworks from a range of sources heavily influence standards and delivery of services. Three distinct 'Levels' of service provision were set out based on the complexity of care: Level 1: asymptomatic care, Level 2: uncomplicated symptomatic (excluding men who have sex with men, male discharge and ulceration) and Level 3: specialist services (DH, 2001). Strategies for improvements in contraception provision and reducing health inequalities in young people, and other vulnerable groups, have since been implemented through the DH's (2013) 'A Framework for Sexual Health Improvement in England'. Services need to continually provide innovative ways of working to increase capacity and keep control of costs (DH, 2013). One such example involves services managing asymptomatic patients through online/ postal sexual health services to free-up specialist services for more complex patients (London Councils, 2017; SH:24, 2017). There are two extremely influential organisations in sexual health that provide an array of evidence-based guidelines for services to follow, these are BASHH (which provides guidelines on genital, STI and HIV screening/ management) and the Faculty of Sexual and Reproductive Health (FSRH: which provides guidelines

on reproductive health/ contraception). These organisations' clinical guidelines provided the benchmark for clinical assessments made throughout this study.

2.3 Demographics of sexually transmitted infections

Despite a 4% (n=19,344) decrease in STI rates between 2015 and 2016, England continues to have high rates of STIs sustaining a major public health concern. In 2016, there were 417,584 new diagnoses of STIs in England; the most common being chlamydia (n=202,546, 49%), genital warts (n=62,721, 15%) gonorrhoea (n=36,244, 9%) and non-specific genital infections (n=36,774, 9%). Under 25 year olds, men who have sex with men (MSM) and black & minority ethnic (BME) groups accounted for having the highest levels of infection (PHE, 2017). A range of issues that influence sexual behaviour and risk include: confidence, religious and culture beliefs, peer pressure, coercion, abuse and interpretation of social norms (DH, 2013). Access to sexual partners, and potential abuse, is easily facilitated through social media, smart phones and the internet (BASHH, 2010). The use of drugs and alcohol is also related to having a higher number of sexual partners and inconsistent condom use (BASHH, 2010). Young people aged 15- 25 are at particular risk of acquiring STIs and unwanted pregnancy because of inexperience, lack of knowledge, inability to negotiate safer sex, vulnerability or abuse (BASHH, 2010; DH, 2013). Young people account for 62% (n=66,701) of heterosexual chlamydia diagnoses, 50% (n-8,896) of gonorrhoea and 49% (n=28,540) of genital warts. Higher rates of infection are found in urban regions, particularly in areas of deprivation where cultural, economic and behavioural influences affect higher risk taking and lower health-seeking behaviours. Urban areas also contain higher concentration of BME groups, putting them at higher risk of STI and unwanted pregnancy (PHE, 2017). MSM are at higher risk due to multiple sexual partners and risker sexual behaviour (e.g. anal sex without condoms). The highest rates of syphilis (n=4,788, 81%) are disproportionately found in MSM (PHE, 2017). There has, however, been a decrease in teenage pregnancy rates, which are now at their lowest levels since records began in 1969. This has been attributed, in part, to the use of long-acting reversible contraception (DH, 2013; PHE, 2017b).

2.4 Modernisation of nursing roles in sexual health

Historically the sexual health nursing role was one of chaperoning and procedural duties (Miles *et al.*, 2002), but since 1996 (Davis, 2008), the role has progressively expanded to include autonomous management of full episodes of care. This involved extending nurses' roles to facilitate an increase in patient capacity by distributing the workload to the most appropriately skilled practitioners (Robinson & Rogstad, 2003; DH, 2013). The specialist sexual health nurse practitioner role involves taking a sexual history, performing a physical examination, making a diagnosis and delivering medications. Nurses are fully responsible and accountable for patients they independently manage (Miles *et al.*, 2002; Roberts, 2005; Keefe, 2008). Nurse practitioners and nurse consultants are now commonplace in sexual health services (MedFASH, 2008; DH, 2013) following the integration of competency-based training, assessment and clinical supervision (Miles *et al.*, 2002; Robinson & Rogstad, 2003). A questionnaire survey of English GUM clinics, which obtained a 91% (n=190) response rate, identified that 78.9% (n=150) of clinics had some form of nurse-led clinic (Miles *et al.*, 2002). Despite such expansion in the sexual health nurses' role since 1996, there was very limited recent evidence found with regards to current advanced practice roles in sexual health.

Nevertheless, nurse practitioners (NP) working within sexual health are expected to practice at a high level of competency to maintain safe, appropriate and cost-effective care (DH, 2013; MedFASH, 2014). Additional competency-based training and HEI qualifications, preferably Masters, are advocated (RCN, 2012). A previous lack of university-based preparedness for sexual health nurses has been noted (Estcourt *et al.*, 2011); however, the education arm of BASHH introduced '*Sexually Transmitted Infection Foundation*' (STIF) training, which acts as an introduction to STI management. STIF Competencies then provide nationally recognised levels of clinical competence from novice to expert, i.e. '*Fundamental'*, '*Sexual health advising',* '*Intermediate'* and '*Advanced'* (BASHH, 2018). Moreover, the '*Diplomate Assessment of the Faculty of Sexual & Reproductive Healthcare*' (DFSRH: FSRH, 2014) and the '*Diploma of the Institute of Psychosexual Medicine'* (Institute of Psychosexual Medicine, 2018) have recently been made available to nurses, after previously being applicable to medical staff only. Although there is a move to introduce BASHH STIF competencies and the DFSRH

as standard across all sexual health services, NP training and assessment is currently governed locally by individual services.

One component that has been consistent throughout the literature is the need for sexual health NPs to have access to medication for STI management and contraception provision (Handy, 2002; Dinsdale & Duffin, 2004; Roberts 2005; Robinson, 2009; DH, 2013; Wilson 2014). Where nurses were working in advanced practice roles in 2002, a range of medication pathways were evident, including: transferring patients to medical teams; doctors prescribed and nurses supplied; medication protocols; and, of concern, a small number of nurses provided medications using retrospectively obtained prescriptions (Miles *et al.*, 2002). One study concluded that sexual health nurses frequently delivered medication, and that nurses who had independent access to medication were more likely to complete episodes of care autonomously, as compared to nurses who did not have independent access (Black, 2013). Therefore, in order to deliver sexual health services effectively and legally, independent access to medication by nurses has always been considered an essential component of their role (Miles *et al.*, 2002; Walsh, 2004; Keefe, 2008; Black, 2013).

The next chapter provides a general overview of the empirical evidence related to the delivery of medicines by nurses, and provides support for this research.

CHAPTER 3: **LITERATURE REVIEW OF EMPIRICAL EVIDENCE**

3.0 Introduction

The significant changes to medication legislation and expansion of nurses' clinical roles in sexual health explored in Chapters 1 & 2 demonstrated a considerable increase in sexual health nurses' clinical responsibility. Nurses' ability to assess, diagnose and manage patients' care episodes is facilitated by independent access to medication. While medication access supports autonomous practice, it is essential that patients receive safe, high quality and cost effective care. This chapter presents a review of the current empirical evidence related to safety and appropriateness of nurse prescribing/ patient group directions (PGDs); patients' experience of nurses' independently delivering medication and the associated cost implications. The literature will demonstrate gaps in the current evidence base to justify undertaking this study; sexual health being an area where nurses regularly deliver medication independently (Courtenay & Gordon, 2009; Black, 2013). This chapter presents the scope of the literature review, detailing the search process, and then presenting the empirical research evidence.

3.1 Scope of review

Nurse prescribing and PGD literature from 2006 onwards was searched as these were more likely to represent nurse medication delivery practice following the significant change in legislation permitting specially trained nurses to prescribe any licensed medicines (and some controlled drugs: DH, 2006). In line with the overall aims of the research, available evidence was identified and analysed under three key questions: (i) to determine if nurses use their access to medications responsibly, rationally and in accordance with clinical standards, (ii) to explore the patient experience of nurses delivering medication, and patient satisfaction as service users, (iii) to investigate the resource and cost implications of nurses delivering medication independently and issues of cost-effectiveness. Due to the limited volume of PGD evidence from 2006, the search dates were subsequently extended to include literature from 2000 onwards, which yielded four more papers. The relevant literature was

searched and scrutinised with the intention of exploring independent nurse delivery of medication within sexual health.

3.2 Search strategy

A comprehensive search strategy was used to search professional and academic journals for literature related specifically to nurse prescribing and PGDs. The terms used to search the British Nursing Index (ProQuest); the Cumulative Index to Nursing and Allied Health Literature (CINAHL); Medline/Ovid/Embase/PschInfo are presented in Table 3-1. Given the focus of the research enquiry, the search strategy focussed specifically on three aspects: 'safety & appropriateness'; 'patient experience' and 'health economics/ cost'. The term 'supplementary' was not included as this type of prescribing is rarely appropriate for sexual health as patients attend infrequently, therefore the creation of clinical management plans (required in supplementary prescribing) are generally impractical. The terms 'prescription*'; 'treatment'; 'formulary' were removed during the search using MedLine/Ovid/Embase/PschInfo databases as results rarely referred to nurses delivering medication. The search areas were connected by: ['Nurse'] AND ['Prescribing' OR 'PGD'].

Table 3-1 Search terms

Search area	Words used in search strategy
Nurse (independent)	[Nurs* OR independent OR non-medical]
Prescribing	[Prescrib* OR access OR prescription* OR treatment OR formulary]
PGD	["Patient group direction*" OR "medication protocols" OR guidelines OR PGD]

Papers' titles were used to initially identify potential articles for inclusion in May 2015. Abstracts were read to determine suitability and relevance to the search criteria. Papers read in full were entered onto a spreadsheet to chart relevant data and summarise papers for potential use in the review. Due to the limited PGD papers, a secondary search was undertaken in July 2015. Figure 3-1 summaries the process taken using a Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) diagram.

The following inclusion/ exclusion criteria were used to determine if an article was suitable for inclusion within the literature review:

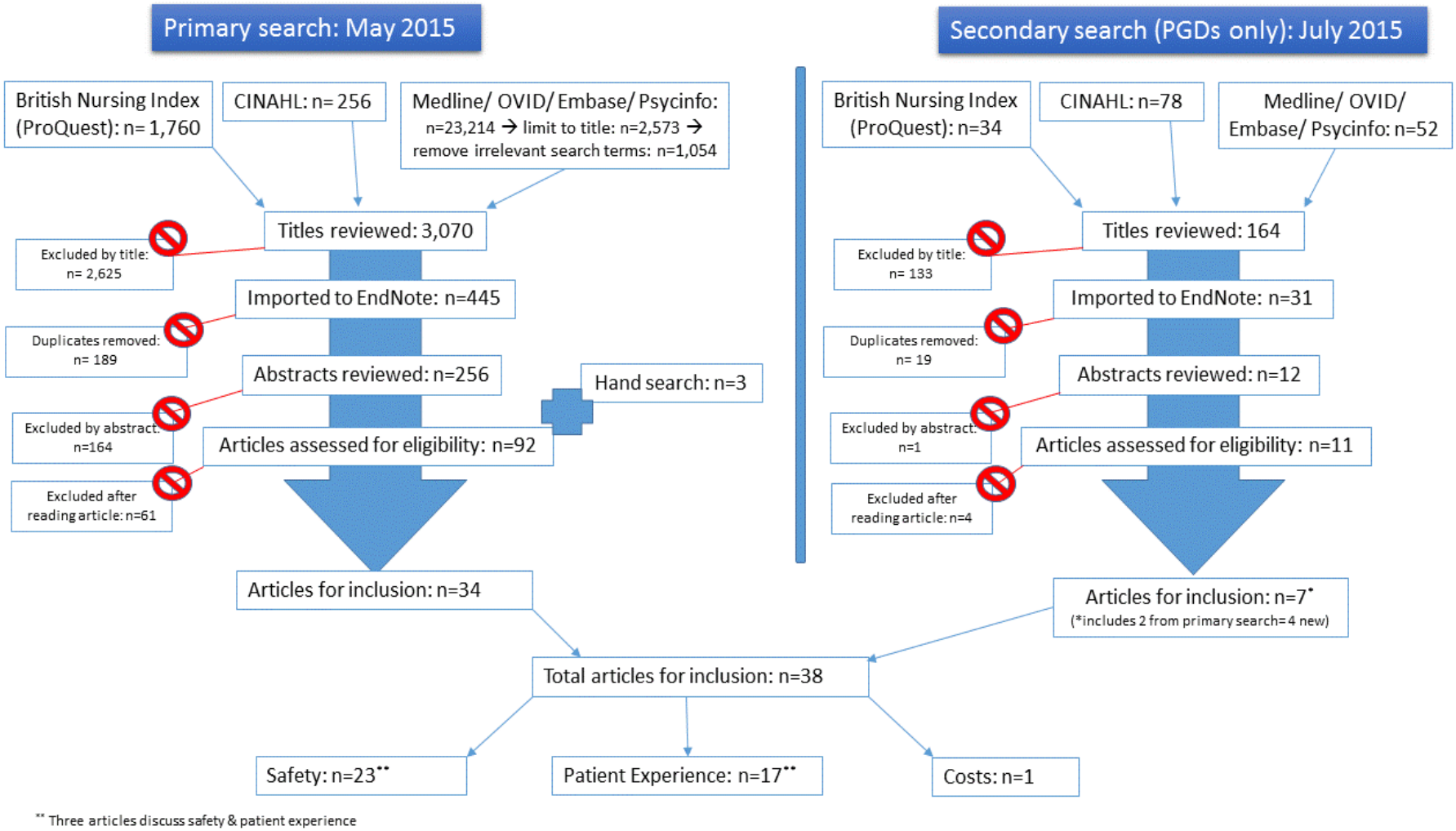
Inclusion:

- Published studies in peer reviewed journals incorporating empirical evidence only (inclusive of research, detailed audits and/or service reviews).
- PGD use after 2000 and independent nurse prescribing after 2006
- Papers published in English

Exclusion:

- Articles not based on primary research, audit or service review
- Studies exploring issues not related to the three key search themes (e.g. nurse/ stakeholders' perceptions, continuing professional development (CPD), training or education)
- Studies assessing supplementary prescribing (search focussed on medication delivery methods likely to be used in sexual health). Exception: Norman *et al.* (2010), which was reviewed as it was the only paper that reported an economic assessment involving independent nurse prescribing or PGD use.
- Papers not in English

Figure 3-1 Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) diagram for search process



3.3 Inclusion of papers and assessment of quality

Thirty-eight papers are included for review in this chapter; three papers had content relating to both safety and patient experience (Courtenay et al., 2009a; Courtenay et al., 2009b; Wilkinson et al., 2014); and nine of the papers made reference to costs/ resources, but did not undertake specific economic assessments. Figure 3.2 outlines the structure of the analysis in this chapter. Papers were categorised as either 'descriptive' or 'evaluative'. For the purposes of this thesis 'descriptive' papers predominantly described existing practice (i.e. based on audit, retrospective notes review) or situations (i.e. qualitative methods or opinions/ attitudes surveys). Papers are presented as 'evaluative' if they used validated research tools to measure outcomes from the collected data. Relevant information from each study is presented in: Table 3-2 Descriptive safety and appropriateness papers studies (10 papers); Table 3-3 Evaluative safety and appropriateness papers studies (13 papers); Table 3-5 Descriptive patient experience papers (15 papers); Table 3-6 Evaluative patient experience papers (two papers); and Table 3-7 Health economics literature (one evaluative paper).

The assignment of 'Strong'; 'Moderate'; and 'Weak' to determine papers' quality is a subjective process (Aveyard, 2014). In order to provide a level of objectivity in assessing the papers' quality, the Critical Appraisal Skills Programme (CASP, 2013) tools were used to support critical analysis. The CASP tools prompt the assessor to consider 12 questions across three sections, involving: validity of the study; consideration of the results; and will the results help locally (CASP, 2013). Papers receiving 0-4 positive responses to the 12 questions were considered weak, 5-8 were moderate and 9-12 were strong. The methodology, sample size, participants involved, detail of the data presented and analysis method were considered in conjunction with relevance to this thesis to assign strength. Overall 18 papers were classified as strong; 21 as moderate; and two as weak. The quality of the paper is presented alongside a summary of its principal strengths (+) and weaknesses (-).

Figure 3-2 Structure of presented papers

Structure of literature review areas and themes

- Safety and appropriateness of nurse prescribing (23 papers)
  - Overview of prescribing errors incidence and nature
    - Three papers: Dornan *et al.*, 2009; Avery *et al.*, 2012; Seden *et al.*, 2013
  - Prescribing practice: doctors versus nurses
    - Four papers: Dornan *et al.*, 2009; Avery *et al.*, 2012; Carberry *et al.*, 2012; Seden *et al.*, 2013
  - Safety of nurse prescribing
    - Seven papers: Latter *et al.*, 2007a; Carey *et al.*, 2008; Carey *et al.*, 2009; Courtenay *et al.*, 2009b; Avery *et al.*, 2012; Black, 2013; Wilkinson *et al.*, 2013
  - Appropriateness of nurse prescribing consultations
    - Eight papers: Latter *et al.*, 2007a; Latter et al 2007b; Courtenay *et al.*, 2009a; Courtenay et al, 2009b; Sibley *et al.*, 2011; Latter *et al.*, 2012; Naughton *et al.*, 2012; Riley *et al.*, 2013
  - Safety of patient group directions
    - Six papers: Miles *et al.*, 2001; Brooks *et al.*, 2003; Deave *et al.*, 2003; Baileff, 2007; Williams & Know, 2011, Black & Dawood, 2014
  - Nurse prescribing versus PGDs
    - One paper: Black & Dawood, 2014
  - Organisational nurse prescribing governance
    - Two papers: Dornan *et al.*, 2009; Smith *et al.*, 2014

- Patient experience and nurse prescribing (17 papers)
  - Patients' expectations of nurse prescribing
    - Five papers: Berry *et al.*, 2008; McCann & Clark, 2008; Banicek, 2012; MacLure *et al.*, 2013; Natan *et al.*, 2013
  - Patients' experience of nurse prescribing
    - 12 papers: Courtenay *et al.*, 2009a; Courtenay *et al.*, 2009b; Hobson et al 2009; Courtenay *et al.*, 2010; Jones *et al.*, 2010; Courtenay *et al.*, 2011; Dhalivaal, 2011; Drennan *et al.*, 2011; Earle *et al.*, 2011; Ross *et al.*, 2013; Wilkinson *et al.*, 2013; Tinelli *et al.*, 2013

- Costs (10 papers)
  - Resource and cost assessments
    - 9 of the papers refer to cost or resources (but no formal assessment): Latter *et al.* (2007b); Carey *et al.* (2008); Courtenay *et al.* (2009b); Courtenay *et al.* (2010); Courtenay *et al.* (2011); Earle *et al.* (2011); Latter *et al.* (2012); Naughton *et al.* (2012); Wilkinson *et al.* (2013).
    - 1 paper cost consequence analysis: Norman *et al.*, 2010

Table 3-2 Descriptive safety and appropriateness papers

Author	Setting & participants	Research aim/ question	Design	Sample size	Key findings	Quality of study
Baileff (2007)	Two walk-in centres, England, UK	To audit the standard of practice on supply and administration of antibiotics in two walk-in centres	Audit assessing clinical records of PGD antibiotic practice against five standards; August 2005	199 patients received antibiotics	10 different drugs used. No evidence of unsafe practice. PMH, allergies (191, 96%) & current medication (188, 94%) consistently recorded; inclusion (191, 96%) and exclusion (190, 95%) criteria largely met; Poorer documentation of contraindications (97, 49%) and side effects (94, 47%). Drugs named 99% (199) but dose poorly documented 76% (151)	**Moderate** + Strong audit design; Defined measurement standards; Good sample size. - Single person (consultant nurse) data interpretation;
Black (2013)	One A&E & one sexual health department, England, UK	To explore the application and safety of non-medical prescribing in an accident and emergency and sexual health department	Cross-sectional comparative design, retrospectively reviewing clinical records; July 2009-June 2010	764 nurse prescribers (382 in both areas) and 490 from non-prescribers (A&E: 235; sexual:255)	569 drugs, 409 patients, 675 diagnoses; frequent prescribing (A&E: 197, 51.6%; sexual 212, 55.5%); 99.8% (568) safe prescribing; poor documentation (sexual: 2) and inappropriate medication for allergy (A&E: 1). Prescribing statistically facilitated independent practice in sexual health (chi-squared, $p<0.001$)	**Moderate** + Large sample size; Random sample used - Single organisation; Single researcher interpretation, open to bias; Validated research tools not used
Black & Dawood (2014)	One A&E & one sexual health department, England, UK	To explore nurse prescribing versus PGDs in an emergency department	Cross-sectional comparative design, retrospectively reviewing clinical records; July 2009-June 2010	235 PGD and 382 nurse prescribers' clinical records	PGD users: 117 individual drugs, 25 different medications; patients provided medication: 32.3% (76). Nurse prescribers: 274 drugs, 29 different medications, 403 diagnoses; patients provided medications: 51.6% (197) patients. Frequency of medication delivery statistically significant (chi-squared, $p<0.001$). Nurse prescribers 99.7% (381) safe medication decisions; 0.3% (1) provision of penicillin to allergic patient. Restrictive PGDs: 11.8% (9) of drugs not covered by the PGD. No difference in independent practice between methods (chi-squared, $p=0.710$)	**Moderate** + Large sample size, although difference in numbers in each group; Random sample used - Single site; Data analysis open to bias; Validated research tools not used.
Brooks *et al.* (2003)	One walk-in centre, England, UK	To assess nurses' record-keeping and knowledge for antibiotic PGDs	Audit of clinical records October 2000 to March 2001	847 antibiotic PGD records	99.3% (841) medications supplied in accordance with PGD. 0.7% (6) of medication given outside PGD restrictions. Poor documentation noted, 63% (534) notes documented allergy or contraindication information. Improvements needed in documentation concluded.	**Moderate** + Random second check of results; Large sample size; Set standards used for assessment - Audit design in single site

Author	Setting & participants	Research aim/ question	Design	Sample size	Key findings	Quality of study
Carberry *et al.* (2012)	Three intensive care units, Scotland, UK	To determine prescribing activity, number and type of prescribing errors and raise awareness of prescribing activity	Audit of ICU prescriptions over 7 different days, Sep-Oct 2011	77 patient prescription charts	1,418 drug entries, 23.8% (338) from nurses. Error rates: overall 2.8% (40); nurses 0.6% (2/388); trainee medical staff errors (33/984, 3.4%); consultant errors (5/73, 6.8%). Error rates statistically different between groups ($p<0.01$; chi squared test), nurses (2/338, 0.6%) being least likely to make errors, consultants (5/73, 6.8%) most likely. Nurses errors: illegible prescription (1); incorrect dose, time or rate (1)	**Moderate** + Audit design in multiple sites; Involved all prescriptions on separate days; Adequate patient size, large number individual prescriptions - Validated tool not used, although standards set using BNF
Carey *et al.* (2009)	Four general practices, England, UK	To explore prescriptions issued to patients with diabetes by nurse prescribers in general practice	Review of written prescriptions against 8 assessment criteria. Oct 2007 – Sep 2008	19 prescriptions across four case study sites. Section from larger study	Prescription compliance: generic prescribing; products; dose & preparation; terminology; written in ink and used appropriate forms (19, 100%); writing dosage number/words (18, 94.7%). Number of days (2, 10.5%); clear accurate frequency/ timing instructions (7, 36.8%); supply quantity (11, 57.9%). Overall nurses wrote appropriate prescriptions; however, extra vigilance required for accurate documentation.	**Moderate** + Multiple sites, large data collection timescale; Used national standards for prescription writing - Low sample size
Deave *et al.* (2003)	20 walk-in centres, England, UK	To explore the extent walk-in centres complied with PGD legislation and nurses complied with documentation	Assessment of PGDs against 21 legal standards, Feb 2001 & review of clinical documentation against standards, Dec 2000- Feb 2001	20 PGD documents assessed & 453 clinical notes (from nine walk-in centres)	7/20 documents contained all legal aspects; all documents included drug description; clinical condition; clinical situation; dosage; frequency; strength; pharmaceutical form (20, 100%). Less consistency: valid from date; staff qualified to use PGD; signed PGD; administration route (each 12, 60%); record-keeping (11, 55%) and expiry date (10, 50%). Clinical notes review identified 65% (5,074/7,823) of required documentation recorded. Drug description, clinical condition & situation consistently recorded (all 98%); relevant warnings (15%), extra contraception warnings (13% of 122 cases) and pharmaceutical form (6%).	**Moderate** + Multiple sites with strong audit design; Large sample of clinical notes reviewed - Data collection at introduction of PGD legislation, likely out-of-date; Low number of PGDs reviewed
Miles *et al.* (2001)	Single site sexual health clinic, England, UK	To audit the supply of medications using PGDs by sexual health nurses	Prospectively audit patients managed by nurses; assess appropriateness of medication delivery. Jan-Apr 2000	408 patient consultations, unclear number of nurses. 36 case notes documentation reviewed	Three separate PGDs: 31.4% (128) nurses consultation required medication; 14.7% (60) doctor prescription; 14.5% (59) by PGD; 2.2% (9) by PGD and prescription. Review of 36 case notes: 37 supply of medication by PGDs (1 patient need medication from 2 different PGDs); 78.4% (29) were compliant, remaining 21.6% (9) clinically appropriate, but outside PGD limitations.	**Moderate** + Large sample size for PGD use, adequate sample size for documentation review - Only two PGDs used not covering sexual infections

Author	Setting & participants	Research aim/ question	Design	Sample size	Key findings	Quality of study
Smith *et al.* (2014)	General nationwide Primary, Secondary and Mental Health healthcare organisations, England, UK	Determine clinical governance strategies in place for non-medical prescribing	Questionnaire surveys non-medical prescribing leaders, Aug 2008- Feb 2009	87 leaders (52% response)	Leaders included PCT (26), acute/ foundation (37) and mental health (23) respondents. Responses identified: non-medical prescribing committee (PCT (P) = 63%; acute (A)= 74%; mental (M)= 50%); Non-medical prescribing policy up-to-date (P= 96%; A= 97%; M= 95%); Up-to-date controlled drugs policy (P= 83%; A=94%; M= 80%); Clear lines of responsibility & accountability (P= 96%; A= 97%; M= 95%); Definition of scope of practice (P= 75%; A= 85%; M= 95%); Systems for managing poor performance (P= 67%; A= 86%; M= 90%).	**Strong** + National survey; Good representation of NHS providers (despite response rate); Coverage of different types of service providers; - Reliance on accurate reporting from one leader at each site
Williams & Knox (2011)	Single Emergency Care Centre, England, UK.	To identify use frequency of PGD use, PGDs are used appropriately and determine if additional PGDs were required.	Audit of clinical records where a PGD was used, over two separate 24 hour periods, four months apart. Assessment against nine standards. 2008	47 separate PGDs in operation. 113 in first audit, 121 in second = 234 notes in total	16/47 PGDs used on both occasions; most commonly used for analgesia (169, 72%), eye care (45, 19%) and vaccinations (12, 5%). Compliance with clinical condition: first audit (1st) 87%; second re-audit (2nd) 96% compliant. Inclusion criteria compliance: 1st 99%; 2nd 96% complaint. Exclusion compliance: 1st 97%; 2nd 98%. Appropriate dose: 1st 89%; 2nd 94%. Quantity of medication: 1st 92%; 2nd 96%. Documentation in clinical records: improved between 1st and 2nd, however no specific data presented. PGD users signed the PGD register: 1st 61%; 2nd 65%.	**Moderate** + Re-audit results included - Single site; Large number of PGDs not reviewed; Limited raw data presented (over reliance on pie charts)

Table 3-3 Evaluative safety and appropriateness papers

Author	Setting & participants	Research aim/ question	Design	Intervention	Sample size	Outcome measures	Tools	Key findings	Quality of study
Avery *et al.* (2012)	15 General Practice sites, England, UK. GPs' clinical records, prescribers and stake-holder	Determine prevalence and nature of GP prescribing errors, explore the causes, and identify defences against error.	Retrospec-tive clinical notes review over 12 months; error specific prescriber interviews; primary care stake-holder focus groups & root cause analysis	Pharmacists assessing clinical records; judgement panel assigning error severity; interviews; root cause analysis	1,777 patient records (2% random GP population) ; 34 interviews for 70 errors; 6 focus groups =46 particip-ants; 15 root cause analyses	Prevalence & classificat-ion of prescribing errors and severity scoring; identify causes of prescribing errors	Prescribing error definition; logistic regression modelling for prescribing error associa-tions; Reason's Accident Causation Model	Error rate 12.2% (737/6048: 95% CI 10.5%-13.6%): 247 prescribing errors; 55 monitoring errors; 427 suboptimal prescribing, 8 legal problems. Most common drug types involved in errors: cardiovascular (41, 16.6%); skin (39, 15.8%); central nervous system (33, 13.4%). 17.8 % (1,200) patients received at least 1 medication. Error risk factors: patients aged 75 years and older (129, 38%); patients receiving 5 or more drugs (471, 30.1%); patients receiving 10 or more drugs (172, 47%). Most common prescribing errors: incomplete information on prescription (74, 30.0%); dose/strength errors (44, 17.8%); incorrect timing (26, 10.5%). Error severity: 42.4% (128) minor; 54.0% (163) moderate; 3.6% (11) severe. Majority of prescribing errors from GP partners (4859, 80.3%); nurses' error rate: 1.0% (60). Prescribing/ monitoring errors not associated with type of prescriber. Modelled prescribing error risk factors: additional prescribed items increases error risk by 16% (odds ratio (OR) 1.16, 95% CI 1.12-1.19, p<0.001); male patients (OR 0.66, 95% CI 0.48-0.92, p=0.013); aged less than 15 (OR 1.87 95% CI 1.19-2.94, p=0.006); aged 65-74 (OR 1.68 95% CI 1.04-2.73, p=0.035); aged 75 and over (OR 1.95 95% CI 1.19-3.19, p=0.008). Risk of nurses making error compared with doctors: OR 1.55 (95% CI 0.47-5.13, p=0.469); Interviews & root cause analysis: range of influences on medication errors, relating to the prescriber, patient, the team, the working environment, the task, the computer system and the primary/ secondary care interface. Education and CPD recommended to improve safety and error avoidance	**Strong** + Large sample size; Multiple sites; Large random represent-ative sample; Panel review/ assessment; Consistent error definition -Low sample of nurses

Author	Setting & participants	Research aim/ question	Design	Intervention	Sample size	Outcome measures	Tools	Key findings	Quality of study
Carey *et al.* (2008)	Six inpatient wards in single district hospital, England, UK. Diabetes patients	Evaluate the impact of diabetic specialist nurse (DSN) on Rx errors and length of stay (LoS)	Quasi-experiment. May – Dec 2005	Care and advice from a DSN	56 patients = 27 before & 29 after intervent-ion	Insulin and hypogly-caemic medication errors and length of in-patient hospital stay	Error classificat-ion chart	Reduction in medication errors from 520 to 146 after DSN intervention; a mean reduction of 21 errors (p=0.016) and 3 days reduction in mean in-patient stay (17.5 days (IQR 10.25-46.75) to 14.5 days (IQR 9.75-32.25: independent sample t-test, p=0.15). Most common errors: medicines not signed as given (340) and incorrect/unclear prescribing (189). Maximum errors in individual patients reduced from 130 to 33 with DSN. Nurse prescribing improves patient education and safety.	**Moderate** + Adequate sample size - Single site & DSN; Confounding factors may influence LoS
Courten ay *et al.* (2009a)	Ten case study sites: primary & secondary dermatol-ogy services (specialist and non-specialist), England, UK	To evaluate the content and processes in nurse prescribing dermatology consultations	Phase two of larger study: collective case study design. Jun 2006 – Sep 2007	Videotaped consultation	40 consultat-ion observant-ions	Compli-nce with prescribing compete-ncies	National prescribing centre competen-cies & structured observant-ion chart	Good consultation communication (33, 100%); sensitive issues managed well (32, 100%); clear instructions regarding medicines (28, 96.6%); associated risks and benefits (230, 92%); allergies not asked (4, 20%); side effects advice (15, 75%). Prescribing improves patient care for dermatology patients.	**Strong** + Multiple sites; Range of service levels; Specialist experts reviewed videos; Validated data collection tools used -Potential of Hawthorne effect
Courten ay *et al.* (2009b)	Nine case study sites: primary, community and secondary care (specialist and non-specialist), England, UK	To explore the practices of diabetic specialist nurse (DSN) prescribers	Stage two of a larger study: collective case study. Oct 2007 – Sep 2008	Videotaped consultation	35 consulta-tion observa-tions	Compli-nce with prescribing compete-ncies	National prescribing centre competen-cies & structured observant-ion chart	Nurses consistent at planning review (yes= 97.1%); identifying chief compliant (94.3%); exploring management (91.4%). Less consistent with considering non-pharmacological options (no= 11.4%); exploring symptoms (11.4%), allergies (5, 14.3%) and OTC/ herbal medications (77%); treatment risks, benefits (5.7%) and side effects (14.2%)	**Strong** + Multiple sites; Range of service levels; Specialist experts reviewed videos; Validated data collection tools used

Author	Setting & participants	Research aim/ question	Design	Intervention	Sample size	Outcome measures	Tools	Key findings	Quality of study
									-Potential of Hawthorne effect
Dornan *et al.* (2009)	19 acute hospital trusts, England, UK. All newly prescribed/ written inpatient medication charts from all hospital sites	Explore the prevalence, nature and causes of prescribing errors made by first year foundation trainee (FY1) doctors.	Prospective inpatient prescribing chart review over seven census days. Qualitative interviews adopting critical incident approach on causes of errors.	Pharmacists assessing clinical records; judgement panel assigning error severity.	124,260 medication orders; 30 interviews	Prevalence & classification of prescribing errors and severity scoring	Error collection forms; Error ratings and classification table; Reason's model of accident causation	Error rate 8.9% (11,077/ 124,260): FY1 8.4% error rate (4190/50,016); FY2 10.3% (3,568/ 34,781); consultants 5.9% (188/3,177); nurses 6.1% (60/977). Nurse versus consultants prescribing errors: OR 1.00 95% CI 0.71-1.39. Admission most likely for an error to occur (13.4%, 5,973/ 11,079); patients 70% more at risk than discharge (OR 1.70 95% CI 1.61-1.80). Most common errors: medication omission (3,272, 29.8%); under-dose (1,221, 11.1%); overdose (936, 8.5%) and strength/ dose missing (815, 7.4%). Doctors rely heavily on pharmacists and nurses to identify errors, FY1 inadequately supported in prescribing. Errors influenced by complex network of contextual factors, most commonly busy stressful work environments and miscommunication.	**Strong** + Large sample size; Multiple sites; Large random representative sample; Panel review/ assessment; Consistent error definition - Low sample of nurses
Latter *et al.* (2007a)	Ten case study sites across primary and secondary care, England, UK. Nurse practitione, midwife, clinical nurse specialists, nurse consultant, walk-in centre nurses	To measure prescribing competencies use in nurses' consultations to measure quality and safety of prescribing practice	Phase 2 of larger study. Non-participant observation (prescribeing competency checklist) & documentation review, 2002-2003	Consultation observations and documentation review	14 purposively sampled nurse prescribers; 118 prescribing consultations from 333 consultations; 132 prescriptions	Frequency of prescribing; use of prescribing clinical competencies; accuracy of written prescriptions & record-keeping	Observation schedule, prescription verification form, patient record data extraction form	Prescribing frequency 2.82 consultations (range 1.58-6.45). Prescriptions well written: strength (86, 99%); dose (110, 95%); frequency (116, 95%); patients' age/DOB (127, 96%). Nurses demonstrated range of assessment and diagnostic skills. All prescriptions appropriate for Nurse Prescribers' Extended Formulary (NPEF). Nurses identified chief complaint (111, 94%); presenting symptoms (110, 93%). Less consistent: allergy (42, 36%); OTC medication (40, 34%); and exploring family history (15, 13%). Good compliance with written prescriptions. Contemporaneous notes made in all cases, but specific details not recorded: diagnosis (21, 21%); management plan (40, 34%); assessment process (56, 47%); and specific prescription details (37, 31%).	**Strong** + Multiple sites/ specialities; Large sample size; Multiple assessors; Use of validated research tools; - Data collection predates current legislation

Author	Setting & participants	Research aim/ question	Design	Intervention	Sample size	Outcome measures	Tools	Key findings	Quality of study
Latter *et al.* (2007b)	Nine case study sites across primary and secondary care, England, UK. Nurse practitioner, practice nurse, walk-in centre nurse, community midwife, consultant nurse and palliative care nurse	To evaluate prescribing decisions from a sample of nurses	Assess-ment of prescribing consultat-ion transcripts. Sep 2004	Seven prescribing experts' assessment	12 nurse prescribers consulta-tions: 84 individual consultat-ion assess-ments(7 assessors x 12 consulta-tion)	Clinical appropriate-ness of nurses' prescribing decisions	Medication Appropriat-eness Index (MAI)	Nurses overall prescribe appropriately on all aspects of the MAI: indication for medication 84% (70), not indicated 8% (7); effective 83% (69), ineffective 2% (2); insignificant medication interaction 63% (53), significant interaction 10% (8); insignificant medication disease interactions 64% (54), significant 8% (7); correct directions 76% (64), incorrect directions 18% (15). Overall appropriateness concluded, however, areas to improve practice and medication safety.	**Strong** + Multiple sites/ specialities; Adequate sample size; Multiple assessors; Validated research tool; - Sampling method biased; Data collection predates current legislation
Latter *et al.* (2012)	Nine case study sites in general practice, walk-in centre and hospitals, England, UK. General practice, walk-in centres and hospitals.	To evaluate the clinical appropriate-ness of nurse & pharmacist prescribers	Audio recorded consultat-ions and clinical notes evaluation.	Assessment of consultation transcripts by medical (10), pharmacist (7) and nurse (3) prescribing experts	100 audio recorded prescribing consultat-ions, 52 from nurses. Four assessors evaluating each consultat-ion (400 assessme-nts)	Clinical appropriate ness of prescribing decisions	Medication Appropriat-eness Index (MAI)	Nurses make appropriate and safe prescribing decisions: indication for drug 93%, no indication 7%; effective for condition (96%), not effective 4%; dosage correct 91%, incorrect 9%; directions correct 88%, incorrect 12%; directions practical 96%, not practical 4%; drug-drug interactions appropriate 97%. Highest area of nurses' inappropriateness: correct directions given (12%) and cost of prescribed drug (16%). Nurses (and pharmacists) safe and appropriate prescribers, although improvements in history taking, assessments and diagnostic skills identified. STATA software: high level of appropriate prescribing: 1.003; SD 1.854. inter-rater reliability: 84.5% (3,381)	**Strong** + Multiple sites/ specialities; Large sample size; Multiple assessors with good inter-rater reliability testing; Validated research tools
Naughto n *et al.* (2013)	Eight hospitals, Ireland.	To evaluate clinical appropriate-	Assessme nt of clinical	Assessment by two expert	25 nurse prescribers , 142	Appropriat-eness of	Medication Appropria-teness	Differences of opinion between reviewers, low inter-rater reliability (Cohen's kappa statistic score 0.19; anything <0.20 is poor). Concordance scores:	**Moderate**

Author	Setting & participants	Research aim/ question	Design	Intervention	Sample size	Outcome measures	Tools	Key findings	Quality of study
	Antenatal, breast care, cardiac, childbirth, dermatol-ogy, diabetes, emergency, geriatrics, intensive care, orthopaed-ics, pain, postnatal, rheumat-ology	ness and safety of nurse and midwife prescribing practice	documenta-tion and prescript-ions Mar-May 2009.	prescribing reviewers	patient records, 208 medicat-ions	prescribing decisions	Index (MAI)	Appropriate medication 95% (197); effective for condition 96% (199). Most disagreement: treatment duration; reviewer 1: 99% (205) appropriate: reviewer 2: 77% (161). Removal of duration increases reliability to 0.41 (moderate reliability), giving moderate inter-rater score. Overall nurses safe and appropriate prescribers.	+ Multiple sites/ specialities; Good sample size; Use of validated research tools - Uses secondary interpretation of clinical notes; Poor inter-rater reliability
Riley *et al.* (2013)	Thirty-five primary care sites, England, UK. GP services & community pharma-cists.	To determine how clinicians responded and acted on patients' cues during prescribing consultations.	Audio recording primary care consulta-tions. Oct 2009-Sep 2011.	Assessment of consultation transcripts.	528 compar-able consulta-tions (GP=208; nurse=208; pharmacist =112); total 51 profession-al	Practition-ers' responses to patients' cues or concerns.	VR-CoDES (Verona Network coding patient's cues and concerns and health provider's responses).	Consultation length: GPs (10.1 minutes; SD=4.6 m); nurses (11.2 minutes; SD=6.5m); Pharmacists statistically spend longer with patients (18.2 minutes; SD= 9.7m; p<0.0001). Pharmacists (81%, 299) & nurses (72%, 517) statistically more likely to identify concerns and act on cues than GPs (53%, 398). Most common reason for not acting: not acknowledging an issue raised by the patient (GP 26%, nurse 14%, pharmacist 10%), redirection (GP 15%, nurse 11%, pharmacist 9%) or interrupting the patient (GP 6%, nurse 3%, pharmacist 1%).	**Strong** + Multiple sites; Good sample size; Validated research tools; Two assessors
Seden *et al.* (2013)	Nine hospitals England, UK. Three teaching; three district; three specialist	To evaluate prevalence, type and severity of prescribing errors	Prospect-ive documenta-tion of errors on prescribing charts	Pharmacist review of prescription charts, expert panel assignment of error severity	4,238 prescriptio ns	Prevalence & classifica-tion of prescribing errors and severity scoring	Error ratings and classificati on table	Error rate: 10.9%, but 43.8% (1857) of prescriptions have errors; range 20% to 60% across sites; 3,011 errors identified; 41.9% (1,264) minor; 54.1% (1,629) significant; 3.6% (109) serious and 0.3% (9) potentially life threatening. Non-medical prescribing: 0.8% (35) of all prescriptions, with 25.7% (9) error rate. Multivariable analyses: overall risk of error increased 14% for each additional item. More errors at admission than discharge (OR 1.16, 95% CI 0.70 to 1.92 p=0.58), not significant. Risk of error not	**Strong** + Large sample size; Multiple sites; Large random representativ e sample; Panel review/

Author	Setting & participants	Research aim/ question	Design	Intervention	Sample size	Outcome measures	Tools	Key findings	Quality of study
	(paediatrics, women & mental health),							linked to grade of prescriber: error rates junior (49.1%; 729/1,484), mid-grade (48.1%; 176/366); & newly qualified (39.8%; 718/1,805) doctors. Nurse prescribers (25.7%; 9/35) had a lower prescribing error rate than consultant doctors (32.4%; 46/142). Multivariate logistic regression modelling: risk of nurses making an error compared with doctors: OR 0.59 (95% CI 0.21-1.64)	assessment; Consistent error definition - Low sample of nurses
Sibley *et al.* (2011)	Ten NHS Trusts; Primary, Secondary and Care Trusts managing diabetic patients, England, UK.	To identify content and participation in medicine discussions between nurses and diabetic patients	Audio-recording of routine prescribing consultation. Jan - Jul 2008	Assessment of consultation transcripts	20 nurse prescribers, 59 routine consultations	Medicine discussion themes; levels of participation in discussions	MEDICODE (validated tool measuring medicines communication)	Mean 4.4 medications discussed per consultation. Predominantly cardiovascular (28.8%) and endocrine (27.5%) drugs discussed. 260 instances of medicine discussion identified. The most frequently raised themes were 'medication named' (231, 88.8%), usage of medication (170, 65.4%) and instructions (126, 48.5%). Less frequently discussed: 'reasons for medication' (22, 8.5%) and 'concerns about medication' (7, 2.7%). Preponderance of initiative score 0.51 (-1 more patient to +1 more nurses), dialogue ratio 0.48 (monologue 0 to dialogue 1)	**Strong** + Multiple sites; Range of diabetic service providers; Good sample size; Validated research tools; Transcripts coded by three coders
Wilkinson *et al.* (2014)	Four localities providing specialist diabetic care, New Zealand	Evaluate the safety and effectiveness of DSNs and inform extension of nurse prescribing	Process and outcome clinical programme evaluation. Apr-Sep 2011	Introduction of DSN	12 DSN; 1,274 clinical records; Stakeholder(GPs 30, team members 19, patients 89); audits from 117 patient notes & 227 Rx. 18 qualitative interviews	Quality, safety appropriateness of DSN prescribing	Prescribing logs; service usage data; surveys; patient and staff interviews; clinical audit; quality of prescription audit,	1,274 patients, 3,402 prescribing events. Patient notes audit (117): no adverse DSN prescribing events; 3.9% (9/227) prescription administration errors: missed signature; registration number; date & amount to dispense. DSN independent practice: 94.2% (3,206/3,402); dual consultations: 2.6% (89); retrospective prescribing: 3.1% (107). Rubric rating for quality, safety and clinical appropriateness of DSN prescribing: excellent. Rubric for DSN prescribing effectiveness in practice: good.	**Strong** + Multiple sites; Triangulation of multiple data collection methods; Large sample size; Review by experts and validated data collection tools

3.4 Safety and appropriateness of nurse prescribing

Twenty-three papers explored safety and/ or appropriateness of independent nurse delivery of medication; 10 descriptive (Table 3-2) and 13 evaluative (Table 3-3). The papers were categorised into seven main themes: 1) overview of incidence and nature of prescribing errors; 2) prescribing practice: doctors versus nurses; 3) safety of nurse prescribing; 4) appropriateness of nurse prescribing consultations; 5) patient group directions safety; 6) nurse prescribing versus PGDs; and 7) organisational nurse prescribing governance. Each of these themes are presented below.

3.4.1 Overview of prescribing errors incidence and nature

Three papers used quantitative methods to explore the incidence and nature of prescribing errors in general practice (Avery et al., 2012) and hospitals (Dornan et al., 2009; Seden et al., 2013) in England. While predominantly focussing on doctors, nurses' prescribing data was also captured; however, nurses prescribed considerably less frequently compared to doctors. A prospective review of medication charts (Dornan et al., 2009; Seden et al., 2013) and retrospective review of clinical records (Avery et al., 2012) determined a range of prescribing error rates ranging from 8.9% (Dornan et al., 2009); 10.9% (Seden et al., 2013); and 12.2% (Avery et al., 2012). Seden et al. (2013) identified a prescribing error rate of 10.9% per prescribed item; however, 43.8% of prescribing charts reviewed contained at least one prescribing error, which has wide-ranging implications for patients' safety. Within GP services, logistic regression identified one in eight patients were at risk of a prescribing error, or, one in 20 items were provided inaccurately (Avery et al., 2012). For each additional drug prescribed, the chance of an error occurring was found to increase by 16% in primary care (Avery et al., 2012) and 14% in secondary care (Seden et al., 2013). Certain categories of patients were found to be at higher risk of prescribing errors, including: the young, the elderly, those on multiple medications and certain disease specific drugs; most commonly cardiovascular, skin and central nervous system. Common prescribing errors in primary care included incomplete information on the prescription including dose/ strength errors and incorrect timing of doses (Avery et al., 2012). Within secondary care omission of medication at hospital admission was the most common error, followed by dosing and prescription writing errors (Dornan et al., 2009; Seden et al., 2013).

Exploring the causes of prescribing errors using interviews, focus groups (Dornan et al., 2009; Avery et al., 2012) and root cause analyses (Avery et al., 2012), multiple organisational and individual factors have been identified as frequently interacting to cause the error. Organisational influences include workload, staffing levels, clinical complexity of the environment/ ward and shift patterns. Individual issues include: a lack of knowledge (drug, therapeutic or of the patient) or lack of continuing professional development; poor labelling, poor handwriting or documentation; inaccurate histories; poor communication or mathematical skills; transcription errors; and distractions (Dornan et al., 2009; Avery et al., 2012). The comprehensive nature of enquiry and large sample sizes associated with these studies provides a solid basis from which the how, when and why prescribing errors occurs within both primary and secondary care services can be understood.

3.4.2 Prescribing practice: doctors versus nurses

Dornan et al. (2009), Avery et al. (2012) and Seden et al. (2013) each utilised a panel of experts to assign severity categories to prescribing errors based on the potential consequences to patients' safety. Scrutinising data specifically from the nursing perspective, Dornan et al. (2009) found that although nurses' error rates were marginally higher than medical consultants, nurses were not unsafe prescribers. Conversely, Seden et al. (2013) found nurses actually had a lower prescribing error rate than consultants. However, nurses had a higher percentage of prescribing errors classified as 'serious' [potential to cause permanent harm] or 'potentially lethal' compared to junior doctors, but were comparable or safer than medical consultants (Dornan et al., 2009; Seden et al., 2013: see Table 3-4). Seden et al. (2013) and Avery et al. (2012) both found nurses were just as safe at prescribing as doctors overall. However, a true comparison cannot be concluded from these studies due to the significant difference in number and types of medicines prescribed by nurses as compared to doctors. Moreover, given the small sample of nurses in each of these studies, a small number of errors made by nurses has the potential to significantly increase nurses overall error percentage rates when compared against doctors, which may not reflect true practice.

Table 3-4 Severity categorisation of prescribing errors and clinical roles

Severity	Grade	Avery *et al.* (2012) PRACtICe study	Dornan *et al.* (2009) EQUIP* study	Seden *et al.* (2013)*
Minor	FY1	128 (42.4%)	1,638 (39.1%)	519 (48.8%)
	FY2		1,400 (39.2%)	496 (39.2%)
	Midgrade		571 (41.1%)	93 (33.6%)
	Consultant		87 (46.3%)	36 (42.4%)
	Nurse**		27 (45.0%)	8 (57.1%)
Moderate	FY1	163 (54.0%)	2,253 (53.8%)	507 (47.7%)
	FY2		1,925 (54.0%)	725 (57.4%)
	Midgrade		703 (50.4%)	166 (59.9%)
	Consultant		82 (43.6%)	43 (50.6%)
	Nurse**		26 (43.3%)	5 (35.7%)
Serious	FY1	11 (3.6%)	220 (5.3%)	35 (3.3%)
	FY2		187 (5.24%)	41 (3.2%)
	Midgrade		89 (6.4%)	15 (5.4%)
	Consultant		17 (9.0%)	6 (7.1%)
	Nurse**		4 (6.8%)	1 (7.1%)
Potentially lethal	FY1		79 (1.9%)	3 (0.3%)
	FY2		56 (1.57%)	2 (0.2%)
	Midgrade		28 (2.0%)	3 (1.1%)
	Consultant		2 (1.1%)	0 (0%)
	Nurse**		5 (5.0%)	0 (0%)

**the full data have not been presented. Percentages relate to the percentage of prescriptions made by each prescriber that had an error in them ** nurses were prescribers, but not presented as bands. FY1/FY2 = Foundation Year [1/2] doctors*

A fourth paper, involving an audit of patient medication charts in a critical care unit, also compared prescribing errors between doctors and nurses (Carberry et al., 2012). Nurses were found to prescribe more frequently and had a lower prescribing error rate than doctors (Carberry et al., 2012). Interestingly, the overall error rate was considerably lower than that reported in the other studies: 2.8% compared with 8.9% (Dornan et al., 2009); 10.9% (Seden et al., 2013); and 12.2% (Avery et al., 2012). However, definitions of what constitutes an error differed between studies, therefore, an accurate comparison cannot be made between these studies. Moreover, across these four studies the patients' clinical complexity was not explored; consequently, accurate clinical comparisons between doctors and nurses cannot be concluded. The lower prescribing error rate in Carberry et al.'s (2012) critical care speciality, compared with the other three papers, supports Sedan et al. (2013) findings that prescribers working in specialist areas (in this case paediatrics, women's health and mental health) are less likely to make prescribing errors, compared with prescribers in generalist clinical areas. It was considered that a comprehensive knowledge of specialist drugs improves safety (Seden et al., 2013); yet, commonly used drugs were also associated with the majority of errors (Dornan et al., 2009; Avery et al., 2012; Seden et al., 2013). A comprehensive knowledge of drugs,

therefore, may not always be a defence against prescribing errors. Additional research by specialist services is required before any generalisable inferences can be made.

3.4.3 Safety of nurse prescribing

Qualitative comments from three papers (Courtenay et al., 2009b; Avery et al., 2012; Wilkinson et al., 2014) have discussed nurses' "quasi-autonomous role" (Avery et al., 2012), where nurses assess patients but request a doctor to write a prescription, and how this negatively impacts on prescribing safety. Findings identified that interruption of a prescriber is a risk to patient safety (Courtenay et al., 2009b; Avery et al., 2012; Wilkinson et al., 2014). The benefit of nurse prescribing was identified by some GPs as a way of improving safety where nurses have autonomous patient management roles (Avery et al., 2012).

Three quantitative papers have specifically explored the safety of nurse prescribing (Carey et al., 2008; Black, 2013; Wilkinson et al., 2013). Carey et al. (2008) explored the impact of a diabetic specialist nurse (DSN) prescriber on medication errors for inpatient diabetic patients, and found diabetic inpatients were less likely to receive medication errors from this nurse due to their addition prescribing training than patients being managed under standard care. Wilkinson et al. (2013) also explored the safety of prescribing by DSNs through a process and outcome clinical evaluation of patient records. All prescriptions were deemed clinically appropriate, despite five minor instances of unclear documentation. Overall the Rubric rating (measure of standard or performance) for safety, quality and clinical appropriateness for DSN was 'excellent' (Wilkinson et al., 2013). A further study using clinical records also found, despite minor documentation issues, nurse prescribers in sexual health and Accident & Emergency (A&E) provided safe and appropriate prescribing decisions (Black, 2013). While these studies consistently found nurses to be safe and appropriate prescribers, there were methodological weaknesses which may affect the reliability of their findings; these include: conclusions based on a single nurse's intervention (Carey et al., 2008); relying on a single researcher's interpretation of medication appropriateness who did not use a validated research tool (Black, 2013); and results from a healthcare system outside the UK (Wilkinson et al., 2013).

Three papers evaluated the accuracy of the written prescriptions (Latter et al., 2007a; Carey et al., 2009; Wilkinson et al., 2013). Nurses were found to produce comprehensive, detailed and accurate prescriptions (Latter et al., 2007a; Wilkinson et al., 2013). Carey et al. (2009) found that although 19 diabetic prescriptions consistently recorded appropriate generic products, dose & preparation and terminology; DSNs were less consistent at recording medication quantity, number of days, timing and frequency. Moreover, while Latter et al. (2007a) found prescriptions were accurate, the subsequent clinical records lacked details of specific aspects of the consultation; specifically, there were documentation omissions for diagnosis, management plans, follow-up requirements and specific prescription details. The need for improved documentation is consistent with Black (2013) and Wilkinson et al.'s (2013) findings.

3.4.4 Appropriateness of nurse prescribing consultations

One paper (Riley et al., 2013) explored the appropriateness of how GPs, nurses and pharmacists react to patients' cues for information during medication consultations in primary care. Pharmacists and nurse prescribers were more likely to identify a cue or concern from patients and act on it compared to GPs. Three further high-quality studies (Latter et al., 2007a; Courtenay et al., 2009a; Courtenay et al., 2009b) utilised the 2001 version of the National Prescribing Centre's (NPC) prescribing framework, which supports communication during prescribing consultations. The NPC framework was used to assess videotaped nurse-patient consultations in dermatology (Courtenay et al., 2009a) and diabetes (Courtenay et al., 2009b), and to create structured schedules in non-participant observations of primary and secondary care consultations (Latter et al., 2007a). Nurses were found to communicate well with patients, identifying the chief complaint, exploring clinical management and providing clear instructions regarding medicines and their associated risks and benefits (Courtenay et al., 2009a; Courtenay et al., 2009b); however, they performed less consistently on enquiring about allergies and over-the-counter (OTC) medicines (Latter et al., 2007a; Courtenay et al., 2009a; Courtenay et al., 2009b). Although nurses believed they provided patients with information on medication side effects, this was not consistently identified during videotaped consultations (Courtenay et al., 2009a). Latter et al. (2007a) highlights that prescribing may have been for minor conditions, and so full and extensive histories may not have been deemed to be

warranted; however, this author also identifies that not taking and recording full medical histories each presentation does not conform to safety guidelines. Courtenay et al. (2009b) point out that the management of chronic conditions means that similar discussions may have taken place in previous consultations. Research by Sibley et al. (2011) designed to measure medicine communication in the consultations of DSN prescribers', identified that DSNs commonly discussed the name and usage of the medicine, and instructions for use; however, in-line with Courtenay et al. (2009a), side effects were less commonly discussed. Furthermore, it was also evident that the majority of the conversation related to asking a question and obtaining an answer, as opposed to exploring patient choice (Sibley et al., 2011).

Three studies (Latter et al., 2007b; Latter et al., 2012; Naughton et al., 2012) explored appropriateness of nurse prescribing using the Medication Appropriateness Index (MAI), a validated research tool for assessing medication appropriateness across 10 areas (see Chapter 4; Latter et al, 2007b). Two of these studies (Latter et al., 2007b; Latter et al., 2012) assessed transcripts from primary and secondary care nurse prescribers' consultations, and one (Naughton et al., 2012) used secondary care clinical records. All three studies concluded that generally medication was indicated and effective for the condition being managed. The MAI's weighted scoring system demonstrated a high level of appropriate prescribing by nurses (Latter et al., 2012). However, concerns were identified in relation to informing patients how to take medication (Latter et al., 2007b; Latter et al., 2012), the duration of regimens (Latter et al., 2012; Naughton et al., 2012), medicine/disease interactions (Naughton et al., 2012) and ensuring cost-effective prescribing (Latter et al., 2012). Qualitative data identified that assessors were overall confident in nurses' history taking, assessment and diagnosis skills; however, in some cases these were areas that could also be improved (Latter et al., 2012). While the findings are encouraging, there are some methodological weaknesses including the prescribing knowledge of assessors and poor interrater reliability between assessors on appropriateness of prescribing (Naughton et al., 2012); quality of audio recording; and consultations where only a single drug was provided (Latter et al., 2007b).

As these studies used multiple assessors, and validated research tools based on actual consultations, the evidence of nurses' competence and safety in prescribing is strengthened. That being said, the use of transcripts and clinical documentation independently may not provide a true reflection of the

consultation, as not all aspects of the consultation can be verbalised or documented (e.g. checking notes, non-verbal communication), and therefore may not be easily visible to the observer, audiotape or camera (Courtenay et al., 2009a; Courtenay et al., 2009b; Latter et al., 2007a). Consequently, nurses may have performed better than recorded in these studies; nevertheless, nurses need to continually undertake comprehensive patient histories to ensure continued safety and appropriateness of medication delivery.

3.4.5 Safety of patient group directions

Six papers evaluated the safety and appropriateness of medication supply and/ or administration through PGDs: one in sexual health (Miles et al., 2001); three in walk-in centres (Brooks et al., 2003; Deave et al., 2003; Baileff, 2007); and two in emergency care centres (Williams & Know, 2011; Black & Dawood, 2014). Miles et al. (2001) undertook an audit of case notes. The restrictive nature of PGDs and the potential risk of nurses using them outside their limitations was evident (Miles et al., 2001). Conversely, Brooks et al. (2003) and Baileff (2007) both investigated the supply of antibiotics in walk-in centres, and found that PGDs were predominantly used safely, appropriately and within their limitations. Baileff (2007) found nurses were not consistent at recording drug contra-indications and discussing medicines' side effects. Furthermore, although the drug's name was always documented, the dose was not. Overall the use of antibiotics was considered safe and appropriate for the presenting complaints and PGD (Brooks et al., 2003; Baileff, 2007). Williams & Know (2011) also identified good overall compliance with PGDs through an audit of 47 separate PGDs, of which only 17 were utilised in the audit timeframes. PGDs were shown to be appropriately used across the nine audited standards, despite incidents in which they were used outside their limitations. Moreover, the audit highlighted the extensive administration required for PGDs, detailing multiple documents each of which required regular updating and auditing to ensure safety governance. Black & Dawood (2014) similarly found that PGDs were used outside their limitations, despite them being clinically appropriate for the condition managed. As PGDs are locally determined these findings may not be generalisable; however, these studies consistently report PGD limitations and their use to supply medicines outside of their restrictions.

Work by Deave et al. (2003) evaluated the legislative compliance of PGDs in walk-in centres. These authors identified that most PGDs failed to adhere to PGD legislation. Deave et al. (2003) explored the quality of nurses' record-keeping in clinical notes, and found only 65% of the expected PGD documentation. Relevant warnings, contraception advice and pharmaceutical form were inadequately recorded. These researchers also identified that nurses failed to provide the specific medication information they provided to patients in the clinical notes. This is consistent with the findings of other researchers who have reported the need for improved documentation (Brooks et al., 2003; Baileff, 2007; Williams & Know, 2011).

3.4.6 Nurse prescribing versus PGDs

One paper (Black & Dawood, 2014) compared nurse prescribing with PGDs. PGD users were less consistent in documentation than nurse prescribers and provided medication more often when aspects of past medical history, concurrent drugs and allergies were not recorded. Patients being managed by nurse prescribers were 2.23 times more likely to have medication delivered than PGD users, despite both groups managing similar patient presentations. While all PGD users' medication delivery choices were clinically appropriate, 11.8% (n=9) were not within the PGD's limitations. There was one episode where a nurse prescriber provided an unsafe medication for a patient with an allergy but no similar episodes with PGDs. Nurse prescribing was found to be more flexible than PGDs, but potentially facilitated increased frequency of medication delivery and potential to make errors. Improvements in documentation for both groups were advised, but more so for PGD users.

3.4.7 Organisational nurse prescribing governance

One paper (Smith et al., 2014) used a questionnaire survey to explore non-medical prescribing governance safety across organisations in Primary, Secondary and Mental Health services. Despite the limited response rate, the authors identify that the response coverage provides an accurate representation throughout England. All respondents reported their organisation held a register of non-medical prescribers, and most had an up-to-date non-medical prescribing policy in place. Secondary care was most likely to operate specific non-medical prescribing governance committees and have

up-to-date controlled drug policies. There were clear lines of responsibility and accountability detailed for non-medical prescribers; however, mental health was more likely to define nurses' scope of practice and have systems for managing poor performance. Despite the majority of services having up to date policies, the process for ensuring supervision and support for newly qualified prescribers was less consistent; on average only 84% of Trusts provided official support for newly qualified prescribers, and only 59% required prescribers to participate in clinical audit (Smith et al., 2014). Given the evidence presented on medication errors it is important that organisational support or monitoring of clinical and prescribing practice is formally undertaken to avoid patients' safety being put at risk.

3.4.8 Conclusions

The incidence of prescribing errors among prescribers varies across healthcare providers involving primary, secondary and specialist services. Error rates across studies range from 2.8% to 12.2% with varying degrees of severity (low: no harm to severe: permanent harm or death) across different healthcare professional groups. While some studies have shown nurses to be safer prescribers than consultant doctors, others have demonstrated that there is no difference in the risk of prescribing error across each health professional group. Consequently, it is not possible to make generalised conclusions in all clinical specialities on how nurses compare against their medical colleagues. Despite reports that areas of nursing practice require improvement (i.e. more comprehensive documentation and history taking, particularly around concurrent medication and allergies), research specifically examining nurses' delivery of medication has demonstrated that nurses are safe and practice is appropriate. PGDs have also been shown to support clinically appropriate medication delivery; however, PGD limitations and restrictions have also consistently led to their inappropriate use, affecting safe and legal practice. Research exploring nurse prescribing and PGDs in specialist services is lacking, and therefore further research investigation is recommended.

Table 3-5 Descriptive patient experience papers

Author	Setting & participants	Research aim/ question	Design	Sample size	Key findings	Quality of study
Banicek (2012)	Post-operative surgical inpatients in a single site hospital, England, UK	To establish attitudes of post-operative patients towards nurse prescribing (based on management of a theoretical medical condition)	Questionnaire survey	57 post-operative patients (95% response rate)	Level of concern about taking medication from a nurse: none 36.8% (21); slight 22.8% (13); moderate 26.3% (15); very much 7.0% (4); extreme 5.3% (3). Confidence between doctor and nurse prescribing: no difference 60% (34); doctor preferred 40% (23). Likelihood of taking medication: no difference 74% (42), more likely if doctor prescribed 26% (15). Concern about taking medication: less concerned if doctor prescribed 18% (10), no difference 82% (47).	**Weak** + High response rate; Previously used questionnaire; Adequate sample size - Single site; Theoretical medical situation in surgery
Berry *et al.* (2008)	Single site rheumatology clinic, England, UK	Assess rheumatology patients' confidence of nurse prescribing, adherence effect and patient concerns	Questionnaire survey; confidence in nurses amending treatment regimens, Mar-May 2005	54 patients (95% response rate)	40% concerned about side effects of medication; 20% concerned about qualifications and experience of nurse to prescribe. Six point Likert scales mean scores: medication function 5.74; possible side effects 5.69; drug interactions 5.65; effectiveness of medication 5.65; medication type 5.50; awareness of medication working 5.41; risks of not taking medication 5.41; answering detailed questions about medication 5.20; action if medication taken incorrectly 5.19; medication alternatives 4.83. 55% stated they have more confidence in doctors than nurse prescribers.	**Moderate** + High response rate; Adequate sample size - Single site
Courtenay *et al.* (2009a)	Ten case study sites: primary & secondary dermatology services (specialist and non-specialist), England, UK	To evaluate the content and processes in nurse prescribing dermatology consultations	Phase two of larger study: collective case study design involving patient questionnaires, Jun 2006 – Sep 2007	165 patient questionnaires (82.5% response rate)	Communication highly rated (no negative ratings from patients): good/ excellent scores: nurses thoroughness of asking about symptoms 84.2%; nurses listening 92.1%; involvement in treatment decisions 87.7%; explained problems of treatment 93.2%; medication information 83.4%; info dealing with condition 87%; time spent 85.9%; nurses patience 86.1%; nurses caring 91.5%. Access to nurse: poor/very poor 1.9% (3); fair/ good 30.4% (48); very good/ excellent 67.7% (107). Continuity of care: poor/very poor 0.7% (1); fair/good 21.2% (29); very good/ excellent 78.1% (107).	**Strong** + Multiple sites; Patients attending different levels of service provider; Good sample size; Good response rate - Potential bias sampling

Author	Setting & participants	Research aim/ question	Design	Sample size	Key findings	Quality of study
Courtenay *et al.* (2009b)	Nine case study sites: primary, community and secondary care (specialist and non-specialist), England, UK	To explore the practices of diabetic specialist nurse (DSN) prescribers	Stage two of a larger study: collective case study patient questionnaires, Oct 2007 – Sep 2008	131 patient questionnaires (?response rate)	Communication highly rated (no negative ratings from patients): good/ excellent scores: nurses thoroughness of asking about symptoms 81%; nurses listening 88.1%; putting at ease 86.9%; involvement in treatment decisions 83.6%; explained problems of treatment 86.4%; medication information 80.5%; info dealing with condition 80.6%; time spent 83.3%; nurses patience 85.7%; nurses caring 87.3%. Continuity of care: fair 3.3% (4); good/ very good 63.1% (77); excellent 33.6% (41). Access to nurse: poor/very poor 4.8% (5); fair/ good 42.1% (48); very good/ excellent 53.5% (61).	**Strong** + Multiple sites; Patients attending different levels of service provider; Good sample size; - Unknown response rate; Potential bias sampling
Courtenay *et al.* (2010)	Seven primary care diabetic services, England, UK	Explore the views of patients with diabetes on the advantages and disadvantages of nurse prescribing	Patient audiotaped interviews, Jan – Jun 2009	41 patient interviews	Patients identified less need for medical input, reduced need to see multiple professionals on each visit and reduced wait for prescriptions. Nurses' appointments were more flexible and easier to access by telephone. Patients had confidence in nurses' prescribing knowledge and communication. Patients expect nurses to speak to doctors if they were unsure. Some patients felt nurses had limited medical knowledge, training and abilities to prescribe and would prefer a doctor to manage new medical conditions or treatment regimens.	**Strong** + Multiple sites; Good sample size; Thematic analysis; Random selection of interviews independently assessed
Courtenay *et al.* (2011)	Patients of seven dermatology nurses across four strategic health authorities in primary and secondary care, England, UK	To explore views of dermatology patients on nurse prescribing	Semi-structured interviews with patients with dermatological conditions, Mar – Jul 2009	42 patient interviews	Patients were supportive of nurse prescribing finding it improved access, efficiency of the clinical services. Telephone contact and information and involvement in treatment decisions were all valued by the patients. This meant treatment plans were realistic and supported adherence. Patients had confidence in nurses as prescribers.	**Strong** + Multiple sites; Good sample size; Thematic analysis; Random selection of interviews independently assessed
Dhalivaal (2011)	Four inner city GP practices, England, UK	Explore patients' attitudes to and experiences of nurse prescribing	Semi-structured interviews, Nov - Dec 2007	15 patient interviews	All participants identified nurse prescribing had a positive impact on their care; 73% (11) finding it was easier and quicker to obtain an appointment; nurses were skilled and competent to manage their care; 86% (13) patients felt nurses provided better medicines information than GPs and felt they had a good relationship with the nurse prescriber	**Weak** + Multiple site - Recruitment difficulties; No clear data analysis; single author/researcher

Author	Setting & participants	Research aim/ question	Design	Sample size	Key findings	Quality of study
Earle *et al.* (2011)	Single mental health case study site, England, UK	To explore the views of service users receiving nurse prescribers' care	Semi-structured interviews, interpretative phenomenological analysis	6 service users	All service users felt nurse prescribers were easily accessible and had developed trusting relationships with their nurse. Service users had confidence in their nurses' abilities and happy to accept prescriptions; often preferring this to standard care. Four did not realise nurse prescribing was 'novel'. Information on the medicine and side effects was beneficial; however, two identified they'd like more medicines information relating to choice, and one on what to do if they forgot to take medicine. Two service users realised some others may prefer to see a doctor.	**Moderate** + Data analysis described; Recruitment strategy described - Single site; Small sample size
Hobson *et al.* (2010)	Four primary and secondary NHS Trusts, England, UK. Hypertension and oncology services	To explore opinions of patients on the development of non-medical prescribing	Semi-structured interviews, interpretative phenomenological analysis, Jan - Aug 2006	18 patient interviews	Patients held nurses in high regard compared to doctors in relation to having more time and better relationships. Training, convenience and location of prescribers were seen as more favourable to patients than the profession. Although some respondents question the depth of nurses' prescribing knowledge.	**Moderate** + Multiple sites; Data analysis described - Non-comparable clinical services
MacLure *et al.* (2013)	General public, nationwide, Scotland, UK	Explore the views of the Scottish general public on non-medical prescribing	Questionnaire survey, content analysis, Nov 2006	1,855 (response rate from 5,000: 37.1%); 27.2% (505) with written comments	Pharmacist prescribing comments (312); generic non-medical prescribing comments (172); other healthcare professionals (79). Nine themes were identified: perception of knowledge and training (253); support for a limited range of non-medical prescribing (159); access to medical records (104); motivation and convenience (86); confidence, faith and trust; privacy and confidentiality (85); risks, controls and continuity of care (51); supervision and conflict of interest (46); communication and cooperation (28).	**Moderate** + National questionnaire - Low overall response rate (although large number of responses); Limited raw data presented

Author	Setting & participants	Research aim/ question	Design	Sample size	Key findings	Quality of study
McCann & Clark (2008)	Community patients with schizophrenia, Melbourne & Victoria, Australia	To explore attitudes of patients with schizophrenia for nurses having prescribing authority	Questionnaire completed during interview using the Factors Influencing Neuroleptic Medication Taking Scale	81 patients	Patient attitudes for nurses prescribing antipsychotic drugs: strongly agree/agree: 53, indifferent: 16, disagree/strongly disagree: 31. Nurses changing dose: strongly agree/agree 47, indifferent: 16, disagree/strongly disagree: 37. Nurses discontinuing: strongly agree/ agree: 48, indifferent: 14, disagree/ strongly disagree: 38. Patients' responses on likelihood to take medications if prescribed by a nurse: no difference 72.2% (57); less likely to take 17.7% (14): more likely to take 10.1% (8). Patients' satisfaction with nurses' knowledge of antipsychotic medication: satisfied with how concerns were managed yes 94.2% (49); satisfied with knowledge of medications 90.4% (47).	**Moderate** + Questionnaire based on existing theoretical framework - Small sample size for quantitative analysis; Response rate not presented; Potential sample bias
Natan *et al.* (2013)	Patients with chronic conditions, on at least one drug and hospitalised within previous 12 months, Israel	To explore attitudes of patients with chronic conditions in relation to nurse prescribing	Questionnaire: correlational study, Feb - Apr 2012.	230 responses (response rate 85%)	60% (138) respondents in favour of expanding nurse authority to manage chronic condition; 10% (23) strongly object but only 31% (73) agree with nurses prescribing, 43.9% (101) strongly disagree with nurse prescribing. Respondents have low level of knowledge on nurses' authority to prescribe (M=1.66)	**Strong** + Good sample size & response rate; Targeted population; Details of questionnaire validation - Non UK study
Ross *et al.* (2014)	One mental health NHS Foundation Trust, England, UK. Stakeholders and patients in adult mental health, older adults and substance misuse	To explore the impact of nurse prescribing on the nurse-patient relationship	Interviews and focus group.	7 client interviews, 9 focus groups (2 clients: plus stakeholders, but not reported here)	Some clients report their relationship with the nurse hasn't been affected by the ability to prescribe, while others have noticed a closer relationship. Some clients report being more open with nurses than psychiatrists. Nurse prescribers were seen as more accessible and preferred to rotational junior doctors due to established relationships	**Moderate** + Data collection & analysis process described; Random coding assessments checked - Single site

Author	Setting & participants	Research aim/ question	Design	Sample size	Key findings	Quality of study
Tinelli *et al.* (2013)	Six general practices in different regions, England, UK	To obtain patient feedback on the impact of nurse & pharmacist prescribers on consultation experiences, relationship, medication access, quality of care, choice, knowledge, patient-reported adherence and control of their condition.	Two cross-sectional postal questionnaire surveys.	294 responses (30% response rate from 975: 149 nurses patients & 145 pharmacist)	Patient feedback on nurses only. Satisfied with nurse prescriber 94.3% (133); advised appropriately on medication 87.9% (124); consultation could be improved 12.8% (18); nurse prescriber understood my point of view 87.2% (123); more time required 24.1% (34); patient asked opinion on medication 48.9% (69). Patient reported they received better care from a nurse 12.7% (17), doctor 13.4% (18), no difference 73.9% (99). Patients felt they received safer care from a nurse 8.2% (11), doctor 20.9% (28), no difference 70.9% (95). 43.3% (61) patients are happier they received medication from a nurse, 18.4% (26) stated they were more likely to take their medication from a nurse. If patients have a concern about a medication they find it easier to raise with nurse 24.4% (33), doctor 30.4% (41), no difference 45.2% (61). Patients feel their condition is better monitored by prescriber 28.0% (37), doctor 22.0% (29), no difference 50.0% (66). Patients feel they are better informed about medication by the nurse 25.6% (34), doctor 25.6% (34), no difference 48.9% (65). Patients feel they are more likely to be asked how medications fit around their routine by a nurse 24.4% (33), doctor 11.1% (15), no difference 64.4% (87).Patients feel side effects are most likely to be discussed by nurse 16.3% (22), doctor 29.6% (40), no difference 54.1% (73). Patients feel their condition is better controlled by nurse 43.3% (61). Patients feel they can get prescriptions quicker from a nurse 21.6% (29), doctor 14.2% (19), no difference 64.2% (86) and easier from a nurse 20.1% (27), doctor 15.7% (21), no difference 64.2% (86).	**Moderate** + Multiple sites; adequate sample size; Comparable response between nurse & pharmacists; Questionnaires posted to all eligible participants, reduces bias -Low overall response rate
Wilkinson *et al.* (2014)	Four localities providing specialist diabetic care, New Zealand	Evaluate the safety and effectiveness of DSNs and inform extension of nurse prescribing	Process and outcome clinical programme evaluation using patient interviews. Apr-Sep 2011	Surveys from 89 patients. Qualitative interviews 19 patients.	Patients report: 96.6% (86) content with DSN prescribing; 2.2% (2) prefer doctor prescribing; 1.1% (1) prefers DSN to check with doctor. DSN extremely knowledgeable about diabetic medications (99%, 87) and patients extremely or very confident in DSN prescribing (7.8%, 84). Patients reported DSN prescribing was more proactive way to manage their condition. Patients found DSN more accessible, convenient and cost-effective than GP. Rubric rating for patient experience: excellent. Patients report good availability of DSN and comprehensive consultations.	**Moderate** + Multiple sites; Triangulation of multiple data collection methods - minimal survey data presented from patients

Table 3-6 Evaluative patient experience papers

Author	Setting & participants	Research aim/ question	Design	Intervention	Sample size	Outcome measures	Tools	Key findings	Quality of study
Drennan *et al.* (2011)	General hospital, maternity unit and a children's hospital, Ireland	To measure patients' satisfaction with medicines consultations and education. Patients' intention to comply to treatment	Cross-sectional descriptive questionnaire survey;	Patients receiving medication from a nurse prescriber	140 (approximately 310 distributed; 45.2% response rate).	Satisfaction with education & consultation process & intention to comply to treatment	Consultation Satisfaction Questionnaire (CSQ) and the compliance intent subscale of the Medical Interview Satisfaction Scale (MISS).	Education & advice (percentage agreement): time given to clarify medication questions 99.1%; information given on times to take medicines 97.5%; frequency of medicine 95.9%; purpose of medicine 97.6%; how to take medicine 94.9%; name of medicine 98.3%; side effects discussed 90.0%. Patients reporting they would like more information on medicines 68.3%. Patients reported satisfaction with the consultation (mean scores closer to 100 mean higher satisfaction) in terms of professional care (90.28); overall satisfaction (85.74); however, perceived time was rated lower (75.68). Overall intent to comply was high (83.47). Largest predictor for intent to comply was patients' satisfaction with time spent with nurse/midwife in the consultation.	**Strong** + Multiple sites; Reasonable response rate & sample size; Validated research tools
Jones *et al.* (2010)	Hypertensive and a renal clinic in one NHS Trust, England, UK	Evaluation of the implementation of nurse prescribing in an acute care hospital	Patient questionnaire, Jul 2005 – Sep 2006	Nurse prescribers and doctor comparison	74 patient questionnaires (61% response rate), 53 renal and 21 hypertensive	Patients beliefs about their medication and satisfaction … with medicines information	Beliefs about Medicines Questionnaire (BMQ); Satisfaction with Information about Medicine Scales (SIMS)	Patient questionnaires: 50 were seen by a nurse, 14 by a doctor. All patients had confidence and trust in their prescriber. Patients had strong beliefs in the value of taking medicines to maintain or improve their health, no difference between doctor or nurse prescribers. Satisfaction scores ranged from 2-17; higher the score, higher satisfaction: Scores 1-10: nurses 12% (6), doctors 29% (4); 11-16: nurses 22% (11), doctors 64% (9); 17: nurses 66% (33), doctors 7% (1). Patients are more satisfied with nurse prescribers (chi-squared, $p<0.001$)	**Moderate** + Good response rate; Validated tools used - Single site; Difference in responses rate between groups

3.5 Patient experience and nurse prescribing

Studies investigated patients' experience of medication delivery from two perspectives: (i) five studies explored the expectations of patients who had not experienced nurse prescribing, and (ii) 12 papers that sought the experiences of those who had. The 17 papers are presented under these two perspectives; 15 descriptive studies are presented in Table 3-5 and two evaluative studies in Table 3-6.

3.5.1 Patients' expectations of nurse prescribing

Five papers explored patients' expectations of nurse prescribing (Berry et al., 2008; McCann & Clark, 2008; Banicek, 2012; Mac Lure et al., 2013; Natan et al., 2013). Mac Lure et al. (2013) received mixed responses from surveyed members of the public on their views of non-medical prescribing. Respondents identified concerns relating to training and competence in the role. While some respondents felt appropriate public awareness on levels of training and supervision would alleviate these concerns, others were strongly opposed to anyone other than doctors making a diagnosis and prescribing. A potential benefit of non-medical prescribing was access to medicines as some respondents reported difficulties obtaining GP appointments; however, access to clinical records and confidentiality was a concern raised by respondents. Mac Lure et al. (2013) concluded that the general public did not fully understand the concept of non-medical prescribing and that further clarification of the roles was required. The survey, however, did take place only six months after the significant change in nurse prescribing legislation in 2006 across Scotland, and had a poor response rate.

Two papers (Berry et al., 2008; McCann & Clark, 2008) used questionnaires to explore theoretical confidence in nurse prescribing; one in rheumatology and another in schizophrenia. While overall support for nurse prescribing was found, both papers identified that only a small majority were in favour of it in their clinical areas. McCann & Clark (2008) found patients were not confident in allowing nurses to modify doses or discontinue medications, despite nearly all respondents reporting they were satisfied with nurses' management of medication concerns, and nurses' knowledge. Conversely, Natan et al.'s (2013) questionnaire survey of patients living with chronic conditions in

Israel found only a third of respondents were supportive of nurses being able to prescribe. Nearly a third (n=69) were supportive of nurses expanding their prescribing authority, however, 44% (n=101) strongly oppose it. Main concerns were relating to nurses not having the necessary knowledge to initiate or change medication without speaking to a doctor. Over half the respondents reported having no knowledge about the remit of nurses prescribing authority. While Israel's healthcare system is not directly comparable to the UKs, the study draws attention to patients' apprehensions when considering significant changes to healthcare delivery, which may have also influenced the publics' opinion found by MacLure et al. (2013). A further paper (Banicek, 2012) explored patients' expectations of nurse prescribing. While the majority of respondents were supportive, a significant number had 'moderate' to 'extreme' concerns about nurses prescribing. Banicek (2012) concluded that although 60% of patients had no preference on whether a doctor or nurse manages the condition, 40% would prefer a doctor to prescribe the medicines. So while there is general support for nurse prescribing, some apprehension is evident. This study did, however, survey post-operative surgical patients about a theoretical medical condition, and therefore may influence the responses obtained. Nevertheless, from 41 qualitative responses, Banicek (2012) identified that half of patients had concerns regarding side effects and medication effectiveness; similar concerns were also raised in Berry et al.'s (2008) work. This in in-line with studies that have explored safety, which have identified information relating to these areas can be lacking (Baileff, 2007; Latter et al., 2007a; Courtenay et al., 2009a; Sibley et al., 2011).

3.5.2 Patients' experience of nurse prescribing

Twelve papers explored patients' actual experience of nurse prescribing using a variety of data collection methods. Two studies used questionnaires in renal/ hypertension clinics and across primary and secondary care (Jones et al., 2010; Tinelli et al., 2013); six undertook patient interviews in: primary and secondary care, diabetes, dermatology, GP practices and (two) mental health services (Hobson et al., 2009; Courtenay et al., 2010; Courtenay et al., 2011; Dhalivaal 2011; Earle et al., 2011; Ross et al., 2013); one observed consultations in secondary care (Drennan et al., 2011); one used questionnaires and interviews in diabetes (Wilkinson et al., 2013); and two adopted a

combination of questionnaires and consultation observations in dermatology and diabetes (Courtenay et al., 2009a; Courtenay et al., 2009b), respectively.

High levels of satisfaction and confidence in nurse prescribing is a consistent theme. Nurses' level of knowledge and experience is held in high regard and patients report that nurses are more accessible than doctors with regards to consultation appointments and accessing medication (Hobson et al., 2009; Courtenay et al., 2009a; Courtenay et al., 2010; Courtenay et al., 2011; Dhalivaal 2011; Earle et al 2011; Wilkinson et al., 2013). Patients consider nurses to be flexible, efficient and able to provide comprehensive information about their condition/ medication (Courtenay et al., 2009b; Courtenay et al., 2010; Courtenay et al., 2011; Dhalivaal, 2011). Good communication in the nurse-patient relationship also facilitates confidence in the nurses' ability to manage conditions, and supports a trusting relationship, continuity of care (Courtenay et al., 2009a; Courtenay et al., 2009b; Hobson et al., 2009; Courtenay et al., 2010; Courtenay et al., 2011; Dhalivaal, 2011; Earle et al., 2011; Ross et al., 2013) and patient involvement in the decision making process (Courtenay et al., 2009a; Earle et al., 2011). Some patients also feel confident that nurses know their limitations, and will seek advice if they are unsure (Courtenay et al., 2010; Courtenay et al., 2011). The experience of patients managed by DSNs has been reported to be 'excellent' (Wilkinson et al., 2013).

While the majority of patients report confidence and satisfaction in nurse prescribing, a very small number express a perceived limitation in nurses' medication knowledge, training and ability to prescribe (Hobson et al., 2009; Courtenay et al., 2010; Courtenay et al., 2011). Additionally, small numbers also report they would prefer to see a doctor if they experienced new medical problems, although they are confident in nurses maintaining or amending established regimens (Courtenay et al., 2010; Courtenay et al., 2011; Earle et al., 2011; Tinelli et al., 2013; Wilkinson et al., 2013). Tinelli et al. (2013) also identified a small number of patients reported some mild dissatisfaction with their nurse prescriber consultations. Although the majority of patients reported no preference in being managed by a doctor or a non-medical prescriber, some patients reported they received better quality and safer care from a doctor than a nurse. Nevertheless, the majority of patients in this study had no preference or preferred the nurse prescriber in terms of quality and access. Nurses scored higher than doctors on access to medications; ease of getting medications; monitoring health; fitting medications around lifestyle; ability to ask questions about medicines; and availability of non-drug

options. Doctors, however, were seen as more knowledgeable with regards to new medications and better informed about side effects (Tinelli et al., 2013). Conversely, Jones et al. (2010) found while hypertensive and renal respondents have confidence and trust in their clinician, patients are more satisfied with nurses over doctors.

Dermatology patients report that their relationship with the nurse and the provision of medicines information supports medicines concordance (Courtenay et al., 2011). Drennan et al. (2011) explored patient satisfaction and intent to comply with medication using a 'Consultation Satisfaction Questionnaire' and the 'Compliance Intent' section of the Medical Intervention Satisfaction Scale (MISS: Meakin and Weinman, 2002). Nurse prescribers scored highly on time for clarification of questions, timing of medication, frequency, purpose, how to take, name of treatment and side effects. However, only 68.3% of respondents felt nurses and midwives provided comprehensive advice and education about medications (Drennan et al., 2011). What additional information would be beneficial was not clear given the high scores in the other areas. Given the diverse range of long and short term conditions managed (e.g. diabetes, cancer, infection) each patients' medication information requirements will differ (Drennan et al., 2011). Overall, patients reported being satisfied with nurse prescribers, finding them accessible practitioners who provide relaxed consultations and appropriate information to facilitate continuity of care and beneficial outcomes (Drennan et al., 2011). Patients overall reported a high intention to comply with medication regimens; however, actual compliance was not measured.

3.5.3 Conclusions on patient experience

Generally, patients' feedback on nurse prescribing is very positive, and more so in UK based studies where nurses' prescribing authority is more established. While the findings conclude patients are generally supportive of nurse prescribing, there is some low lying trepidation in relation to nurses initiating new medication, which is more evident in studies that have explored patient perceptions, rather than actual experience. Nevertheless, patients feel confident in nurses in terms of access to appointments/ medication, nurses' specialist knowledge and communication during consultations. An issue raised in a commentary by Latter (2011), however, highlights that patient experience studies

self-select patients for inclusion which may bias the overall picture. Indeed in this review, 11 studies involved the selection of patients by nurses to include in interviews, observations and questionnaire studies (Courtenay et al., 2009a; Courtenay et al., 2009b; Hobson et al 2009; Courtenay et al., 2010; Jones et al., 2010; Courtenay et al., 2011; Dhalivaal, 2011; Drennan et al., 2011; Earle et al., 2011; Ross et al., 2013; Wilkinson et al., 2013). Tinelli et al. (2013) was the only patient experience study that posted questionnaires out to all participants. Consequently, their work appears to have a wider spread of patient preferences and attitudes towards prescribing compared to the other 11 experience studies reviewed. This could confirm Latter's (2011) comments relating to biased participant populations when exploring patient experience. Researchers should, therefore, facilitate data collection methods that target all patients to reduce selection bias.

While there is a growing evidence base supporting nurse prescribing, there is no evidence available that has explored patients' experience of PGDs. Moreover, no studies were found relating to patients' experience of nurses independent practice in sexual health. Consequently, based on this literature review the thesis will compare and contrast patients' satisfaction and confidence in sexual health nurses using nurse prescribing and PGDs.

Table 3-7 Health economics literature

Author	Setting & participants	Research aim/ question	Design	Intervention	Sample size	Outcome measures	Economic analysis	Key findings	Quality of study
Norman *et al.* (2010)	Five mental health NHS Trusts, England, UK. Patients diagnosed with depression, anxiety or schizophrenia for minimum six months being managed in NHS units employing supplementary nurse prescribers.	To compare the outcomes of patients prescribed medication by mental health supplementary nurse prescribers with consultant psychiatrists	Post-test control group experiment; which involved matching characteristics of patients in an existing intervention group with one of similar characteristics in the control group.	Assessment of supplementary prescribers compared with consultant psychiatrists	Sample size calculation =60 per group. Achieved 45 matched pairs (80% power) = 90 patients	Medication Adherence Report Scale (MARS); Satisfaction with Information about Medicines Scale (SIMS); Beck Depression Inventory (BDI: 0-63, 63= severe depression); Work & Social Adjustment Scale; Short assessment of Adverse Effects of Antipsychotic Medication Checklist; Client satisfaction Questionnaire	Cost of intervention (i.e. costs of training and CPD); consultation costs; Service costs based on Client Services Receipt Inventory (CSRI): service use data and unit costs; use of health & social care services and informal care. Cost consequences analysis	Medical prescribers' patients (BDI: 20.69) more depressed than nurses' patients (BDI: 17.95). Psychiatrists' patients had greater number of contacts with other therapists (35.0) than nurses (10.1); and psychiatric day care (nurse 14.5, medical 56.0). Inpatient user costs higher for nurses (£2,049) compared with medics (£863). Fewer medical patients (9%, 4) required in-patient care compared with nurses' patients (20%, 9). Nurses annual costs £803 (95% CI -£1,341-£3,020) more expensive without informal care and £1,713 (95% CI -£3,950-£6,699) with informal care included; however, difference is not statistically significant. Bootstrapping found nurses always more expensive than psychiatrists, but not statistically significant. Supplementary prescriber training is additional £497 to each patient. Doctors' time for supervision was not included.	**Moderate** + Multiple sites; Robust and detailed HE assessment; Several outcome measures; - Low recruitment, which may impact conclusions; Covers supplementary prescribing; Cost analysis did not include prescribing training for nurses, or doctor supervision

3.6 Costs

There is no evidence available that has explored the economic implications of nurse independent medicines delivery. Even though strictly outside the search criteria, only one study, a cost-consequences analysis, (Norman et al., 2010) was found. This work is discussed alongside the resource implications raised by other studies. Refer to Table 3-7.

3.6.1 Resource and cost assessments

Overall, the literature search highlighted an absence of consideration of economic implications associated with INPs and PGDs. While the majority of the articles, presented in the safety and patient experience sections, mention enhancing care and providing more efficient service delivery, most do not provide quantifiable evidence on cost or resource outcomes. Three studies in diabetes (Courtenay et al., 2009b; Courtenay et al., 2010; Wilkinson et al., 2013) and one in dermatology (Courtenay et al., 2011) state that nurse prescribing has facilitated an efficient, smooth and flexible service from both staff and patients' perspectives. These papers demonstrated reduced time spent by doctors supporting nurse management of patients, and reduced waiting times for healthcare practitioners to get prescriptions signed. Patients described a more efficient service with improved access to medication (Courtenay et al., 2010), and being managed by fewer healthcare professionals (Courtenay et al., 2011). Wilkinson et al. (2013) also found that increased access to nurse prescribers in New Zealand saved diabetic patients money as they could liaise with the nurse prescriber for free, thus avoiding paying for GP consultations; an issue not relevant in the British NHS as all care is free at the point of delivery. These findings, based on perceptions rather than evidence of actual savings or increased capacity, indicate the need for robust cost assessments to investigate the impact of nurse prescribing on resources required to manage patients. Many factors need to be considered, including nurse training. Earle et al. (2011) determined that an individual mental health nurse becoming an INP was required to undertake approximately 29 clinical supervision training days, keep a reflective diary, pass examinations and undertake 70-80 hours of study via a flexible course. A consultant grade doctor was also required for clinical supervision and training. Furthermore, after the nurse qualifies, they

are required to attend prescribing fora every two months, and undertake personal continuing professional development (Earle et al., 2011); as per NMC requirements (NMC, 2006). So while nurse prescribing is perceived to improve service delivery, the training required to introduce and maintain the skill has cost and resource implications. These need to be fully investigated in comparative studies that cover staff costs, consultation length, prescribing and referral patterns and patient outcomes.

Three further studies discussed costs in relation to assessments using the Medication Appropriateness Index (MAI: Latter et al., 2007b; Latter et al., 2012; Naughton et al., 2012). Latter et al. (2007b) and Naughton et al. (2012) detail that nurses had restrictive choice for medications, therefore a review of costs was not undertaken. Latter et al. (2012), however, found 84% (n=44) of nurse prescribing decisions chose the cheapest appropriate medication. The remaining 16% (n=8), where cheaper alternatives could be used, were related to the management of long term conditions; indicating, according to the interpretation of the authors, that nurses may be reluctant to alter existing treatment regimens, despite the product being more expensive.

A further study explored the impact of introducing an in-patient diabetic specialist nurse (DSN: Carey et al., 2008). The findings indicated that the intervention reduced the median length of hospital stay by three days. While this difference was not statistically significant (p=0.15, t-test), it equated to an expected saving of £168,000 per year in the management of diabetic in-patients in a single hospital trust. The authors suggested that this saving would be enough to employ another DSN. The prediction is based on an assessment of one DSN in a single hospital, and may not therefore be generalisable. However, this study does indicate the potential for significant cost savings that deserve to be investigated further.

While the search yielded no independent nurse prescribing or PGD empirical papers specifically relating to health economic assessments, one paper (Norman et al., 2010) was identified (during the screening of abstracts) that undertook a health economics assessment related to supplementary prescribing. As no other papers were found providing health economic assessments in nurse prescribing and/ or PGDs, this paper was reviewed (Table 3-7). It compared the overall costs associated with the clinical management of mental health patients between consultant psychiatrists and nurse supplementary prescribers. Despite psychiatrists' patients having higher Beck Depression Inventory (BDI) scores and utilising additional therapists more

frequently, supplementary nurse prescribers were found to be £1,713 (including informal care costs) more expensive in the management of the study population than consultant psychiatrists. A large confidence interval does, however, exist and these cost differences were not statistically significant. The higher nursing costs were largely attributable to the fact that twice as many of the nurses' patients received inpatient care compared with doctors. Therefore, five patients who required in-patient care more than doubled the nurses' costs creating a large impact on the health economics assessment. The outcome could be down to chance, given the small numbers involved, but further investigation is indicated to determine the costs effectiveness, and the competence of nurses' independent management of patients. A lateral search of Norman et al.'s (2010) reference list did not identify any further empirical health economic assessment papers.

3.6.2 Conclusions

There is a noticeable scarcity of research that provides a robust health economic assessments on the costs versus the returns of nurse prescribing and/ or PGD use. The only comprehensive costs assessment paper available, has evaluated supplementary prescribing in mental health services managing depression, anxiety and/or schizophrenia. This study concluded that there was no statistical difference in service utilisation costs for managing patients between consultant psychiatrists and nurses; however, nurses' management did appear to be more expensive. It should also be borne in mind that doctors' medication training is integral with their pre-registration education, however, nurses need to obtain further resources in order to obtain independent medication delivery authorisation. There is a need for further investigations to explore the costs of nurse prescribing interventions and to evaluate benefits to the NHS and to patients.

3.7 Chapter summary

This literature review has demonstrated that providing patients with medication is a complex process involving consideration of appropriateness, clinical safety, patient involvement and cost. Medication errors frequently occur within practice, both in primary and secondary care (Avery et al., 2012; Seden et al., 2013). Despite nurses being less experienced at prescribing than doctors, both professions are comparable in terms of clinical safety (Avery et al., 2012). Nurses, however,

often provide better quality patient experience, although some patients may prefer doctors to initiate new medication regimens (Tinelli et al., 2013). Despite this, studies that have specifically explored nurse prescribing have frequently and consistently shown nurses to provide safe and appropriate practice, valued by patients who experience it. Nurse prescribing studies have adopted validated tools (MAI and NPC Prescribing Competencies) to undertake robust investigations. Nurses were overall found to be safe and appropriate prescribers; however, a small number of issues with regards to clinical history taking, patient assessment, documentation, advice and low levels of inappropriate medication choices were also highlighted (Latter et al., 2007a; Latter et al., 2007b; Courtenay et al., 2009a; Naughton et al., 2012). Studies that have specifically explored PGDs have also demonstrated clinically appropriate medication delivery; however, PGD limitations and use outside of their restrictions have been consistently demonstrated. Further studies exploring how PGDs are applied in clinical settings are therefore essential to inform practice and ensure safe and legal PGD use (Deave et al., 2003; Black & Dawood et al., 2014). There is limited literature to be found that has explored the cost effectiveness or resource implications for nurses independently delivering medication. The literature did, however, highlight presumed cost benefits; however, only one study undertook a health economics assessment (Norman et al., 2010), and found supplementary mental health nurse prescribers were more expensive at clinically managing patients than consultant psychiatrists (excluding additional professional training resources required by nurses post-qualification). In order to ensure value for money and justification of resources, more health economics evidence evaluating the costs versus the returns is required.

The literature review identified that medication errors may be less frequent in clinical specialties than in more general clinical areas (Carberry et al., 2012; Seden et al., 2012); however, more evidence is required before this can be substantiated. Sexual health services have modernised and expanded the nurses' role to enable them to independently manage episodes of care (see Chapter 2). As sexual health services commonly use both PGDs and nurse prescribing, this specialty provides an excellent platform to explore nurses' medication delivery, and the associated patients' experience and cost implications. Given the considerable gaps in the current evidence base, this study sets out to explore and quantify the impact nurse prescribing and PGD use has on sexual health nurses, service delivery and patient experience.

3.8 Papers published after initial literature review

From 15th May 2015 until the 31st March 2018 automated weekly search results were emailed to the researcher using the original search criteria. This process highlighted 82 results which represented 46 papers (after duplicates were removed). Removal of non-relevant papers by titles or non-empirical research resulted in 24 abstracts being reviewed. After reading 12 papers in full, four papers met the original search criteria: one related to clinical care, patient experience and cost-effectiveness (Courtenay et al., 2015); one related to nurse prescribing safety (Hyde et al., 2016); one explored patients' experience (Courtenay et al., 2017b); and one related to cost-effectiveness of non-medical prescribing (Noblets et al., 2018). Courtenay et al. (2015) compared general practice diabetic patients being managed by INPs with non-INPs using a matched case study design. This involved 12 GP practices participating in staff interviews, clinical notes review, observations and clinical diaries and patient interviews. There was no difference found with regards to patients' clinical outcomes (except a reduction in the BMI of INP's patients) between prescribers and non-prescribers. However, prescribers' consultations were longer and they were on higher salaries compared to non-prescribers. Non-prescribers needed support and prescriptions from the GP more frequently. Nevertheless, non-prescribers were found to be less expensive compared with prescribers despite non-prescribers needing additional GP resources. However, patients reported being overall more satisfied with prescribers.

Hyde et al. (2016) undertook a survey of 300 nurses, radiologists and medics across Ireland to determine perceptions of risk and safety of INPs prescribing ionisation radiation. Obtaining 167 responses (55.7% response rate), they identified professional barriers which were still evident with regards to perceptions of the safety of nurses prescribing; predominantly from radiologists who could not prescribe (when this study was undertaken: Hyde et al., 2016). This was despite existing evidence demonstrating nurses' safe and responsible prescribing practice elsewhere (as previously reported). With regards to patient experience, Courtenay et al. (2017b) identified, through 120 patient questionnaires and 22 interviews, that although some patients with respiratory conditions expected antibiotics (43%), patients more frequently sought information (58%) and reassurance (52%) regarding their condition, or a physical examination (44%). Moreover, nurse prescribers avoided antibiotic prescribing through 'patient-centred management'

which provided education and reassurance rather than antibiotics. Overall, 96% of patients were satisfied with nurse prescribers' consultations, however, those expecting antibiotics, and didn't receive them, were less satisfied with treatment decisions (Courtenay et al., 2017b). With regards to health economics, Noblets et al. (2018) undertook a systematic review to determine the clinical and cost effectiveness of non-medical prescribing, and in line with the literature search undertaken by the researcher, found very limited evidence on this topic. One study exploring pharmacist prescribers vs. secondary care prescribing for pain was discussed. When adjusted for baseline clinical costs, pharmacists were more expensive than treatment as usual. This strengthened the need for more cost-effectiveness research with regards to the impact of non-medical prescribing on service delivery.

CHAPTER 4: **METHODS**

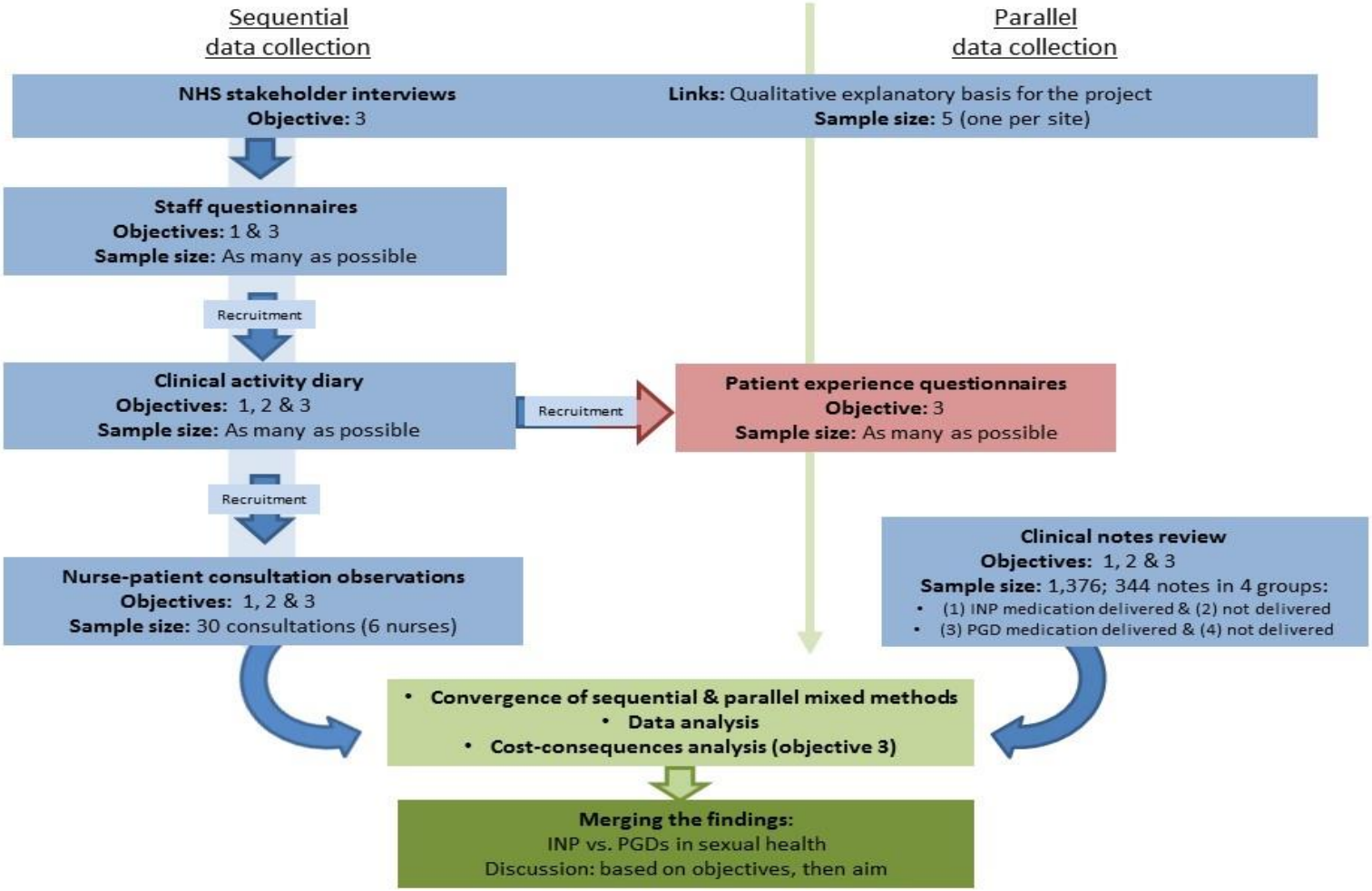
4.0 Introduction

Based on the evidence gaps presented in the preceding chapters, this study compared and contrasted sexual health nurses' use of INP vs. PGDs. A health services research approach (Bowling, 2009) was adopted to determine the provision, effectiveness and practicalities across three core themes: the clinical impact of nurses' medication delivery; patients' experiences of nurses delivering medications; and estimated costs associated with each approach.

In practice, "*medicines management is not a tag-on at the end of a consultation but is dependent upon and part of the whole consultation*" (Cushing and Metcalf, 2007, p.1055). Due to the multiple considerations and perspectives required to comprehensively explore this topic, and to obtain the most clinically valuable outcomes, a mixed methods design (Creswell, 2014) was deemed by the researcher as the most appropriate. The 'Mixed Methods' approach employed seven separate data-collection 'tasks', involving: [clinical] NHS staff stakeholder interviews; staff questionnaires; clinical diaries; clinical notes review; observations of nurse-patient consultations; [patient] patient experience questionnaires; and [cost] a health economics/ cost assessment. The interactions between these tasks are summarised in Figure 4-1.

Due to the complexity of the study, this chapter presents an overview of methods. Methods specific to each 'task' are subsequently presented alongside their findings in the next chapter. The methods overview presents: an outline of the project's design; the study's aims, objectives and research question; justification for employing a mixed methods design; an overview of the specific methods used; patient public involvement; inclusion/ exclusion criteria; site selection; an overview of data analysis; study-wide ethical considerations; research project governance; defining errors in prescribing; and determining how safety and appropriateness were measured.

Figure 4-1 Overview of methods



4.1 Research design outline

A convergent mixed methods design (Creswell, 2014) collected qualitative and quantitative data in parallel, analysed each component separately, and then merged data (see Figure 4-1) to generate descriptions, inferences and conclusions. Quantitative data were collected in clinical diaries, a clinical notes review and through questionnaires. These data supported descriptive overviews of nursing demographics; generalisable inferences relating to clinical practice; and patients' satisfaction with nurses independently delivering medications. Qualitative data were collected in parallel through stakeholder interviews and consultation observations. A high-level costs assessment was undertaken based on all of the data collected. Collecting both quantitative and qualitative data in this manner created a deep, yet generalisable, research design which was sympathetic to the complex interaction of how sexual health nurses' independent delivery of medications affected individual nurses, patients and the wider NHS.

4.2 Aim and objectives

Aim:

To explore how sexual health nurses' use of independent nurse prescribing (INP) compared with the use of patient group directions (PGDs) in terms of clinical application, patients' experience and cost.

Objectives:

1. Determine the extent to which sexual health nurses' professional experience and scope of practice affected prescribing practice or PGD use.

2. Explore INP practice and the use of PGDs by nurses working in sexual health services; investigating frequency, range, appropriateness, safety and outcomes of medicines delivery.

3. To assess whether and how local application of INP and/ or PGDs has benefited patients, health professionals and the NHS, with reference to quality of care, appropriate management of sexual health care episodes, and value for money.

How data collected through the multiple methods aligned with the objectives is presented in Table 4.1. This table is structured to align with later discussion sections (see Chapter 6).

Research question:

How does sexual health nurses' use of INP compare with the use of PGDs in terms of clinical application, patients' experience and cost?

4.3 Mixed methods paradigm's influence on research design

'Mixed methods' combines influences from positivist (absolute scientific truth) and interpretivist (subjective interpretation of experiences) paradigms to create a pragmatic approach (Creswell, 2014; Gerrish & Lacey, 2010). The pragmatic approach in this study, made the investigation of nurse delivery of medication the main driver for determining the research methods; as opposed to the study's aims and objectives being restricted by a specific method. The benefits of pragmatism, according to Creswell (2014), is that the researcher is not committed to one philosophy or reality, allowing greater choice of methods. However, mixed method designs are criticised for adopting opposing theoretical contexts, reducing the validity of their results (Bowling, 2009). Yet as nurse delivery of medication is a complex process, a singular research approach would not have provided the comprehensive exploration required to achieve the study's aim. Moreover, the use of multiple mixed methods in this study strengthened the overall design, and validity, by addressing inherent weakness in individual methods and triangulating the findings to achieve more reliable, valid and comprehensive conclusions (Creswell, 2014; Gerrish & Lacey, 2010). Consequently, these methods will generate new nursing epistemological knowledge through expert nursing experiences and robust empirical data collection (Chultz and Meleis, 1988) and new ontological knowledge through exploring the process of how nurses care (Reed, 1997).

Table 4.1 How methods align with the discussion in Chapter 6

Objective sub-section	Method					
	Staff interviews	Staff questionnaire	Clinical diary	Clinical notes review	Observation study	Patient questionnaire
Professional experience of those delivering medication	✓	✓			✓	
INPs & PGD users' scope of practice	✓	✓				
Frequency of medication delivery			✓	✓		
Range of medication				✓	✓	
Appropriateness of medication delivery				✓	✓	
Safety of medication delivery	✓			✓	✓	
Consultation characteristics			✓	✓	✓	
Autonomous practice	✓	✓	✓	✓	✓	
Consultation duration			✓		✓	
Benefits to patients	✓	✓			✓	✓
Benefits to health professionals	✓	✓				
Benefits to NHS	✓	✓				
Quality of patient care				✓	✓	✓
Appropriate management of genitourinary & reproductive care				✓	✓	✓
Value for money	✓	✓	✓	✓	✓	✓

4.4 Overview of methods

The study involved five separate sexual health sites located in cities throughout the UK mainland. The process and rationale for selecting specific sites are presented in ‘4.8 Study sites and settings’ (page 93). The seven data collection methods used in this study are summarised below:

Staff interviews

The staff interviews (schedule Appendix A) formed a qualitative basis to the project. They explored the governance benefits and barriers of nurses independently delivering medications. Purposively sampled senior NHS staff members participated in semi-structured interviews. Interviews were audio taped, transcribed verbatim and thematically analysed.

Staff questionnaires

The staff questionnaires explored nurses’ demographics, opinions on medication delivery and costs associated with training. All nurses using INP or PGDs at the five sites were invited to participate. Specific questionnaires for INPs (Appendix E) and PGD users (Appendix F) were distributed to all eligible staff. The last section of the questionnaire invited nurses to declare an expression of interest for participating in the clinical diary.

Clinical diary

The clinical diary (Appendix G) involved participating nurses keeping a record over a 2 week period of patients they managed; detailing patients’ clinic numbers and coded responses for: attendance type; whether medication was delivered and if it was done so independently; whether the nurse needed clinical and/ or medication support; who nurses sought support from; and approximate time spent managing patients. Explanatory notes for the codes were detailed on the diary’s front page (Appendix H). Participants were requested to distribute patient questionnaires to all patients who received medication during the 2 week period.

Patient experience questionnaire

A patient experience questionnaire (Appendix L) involved patients completing a two-page questionnaire that explored patients' confidence in nurses' management of their care episode, and satisfaction with information about medicines. The questionnaire was based on validated research tools: STI clinic patient satisfaction survey (Weston et al., 2010) and Satisfaction with Information about Medicines Scale (SIMS: Horne et al., 2001). Patients were requested to return the completed questionnaires in boxes situated in reception areas prior to leaving the department. There was an optional prize draw, to win one of ten £20 high street vouchers to encourage responses. The questionnaire was also distributed to patients in the observational study.

Clinical notes review

The researcher's review of patients' clinical notes randomised a sample of INP and PGD users documentation of patients' presentations over a six-month timeframe (01/07/2015 to 31/12/2015), sourced from clinic attendance lists. Assessments of safety and appropriateness were based on local and national sexual health guidelines/ legislation (BASHH, 2016; FSRH, 2016; NICE, 2014; The Human Medicines Regulations 2012; NMC, 2006; DH, 2006) and the validated Medication Appropriateness Index (MAI: Hanlon et al., 1992), which measures appropriateness of medication provision based on 10 specific areas (see section 5.8.2.1 on 146). Clinical records from nurse-patient consultations were included for review under four distinct categories (presented in Box 4.1) to determine if medication was (i) given appropriately, or (ii) appropriately not given. Anonymised data were recorded on a specifically designed Microsoft Access® database (Appendix K).

Box 4.1: Research categories

1. Medication episodes primarily managed by INP
2. Medication episodes primarily managed by PGD
3. Medication NOT provided in episodes managed by INP
4. Medication NOT provided in episodes managed by PGD

Observations

Nurse-patient medication consultations were observed by a single observer, audio recorded and transcribed. Nurses who participated in the clinical diary were invited to participate. To keep data collection and analysis manageable, six nurses (three INP and three PGD users) from across all five sites were sought to participate. Five consultations were observed for each nurse (n=30 in total). The Royal Pharmaceutical Society's (RPS) 'Prescribing Competency Framework' (2016), which described the competencies central to prescribing, formed the analysis basis of prescribing consultations. The observation schedule was based on an earlier version by NICE (2012: Appendix O). Transcripts were compared against local and national policies for the management of sexual health presentation (STI management and contraception provision). To support deeper analysis and triangulation, the observations were also assessed against the data collection tools used in the clinical diary, clinical notes review and patient experience questionnaire.

Cost assessment

The costs assessment utilised data collected from the preceding methods to compare the costs versus returns between INP and PGDs from the perspective of the individual nurse, the patient and the NHS. The resource and cost implications for setting up and maintaining nurses' independently delivering medication in sexual health were synthesised in a 'Cost & Consequences Analysis' and presented as a balance sheet. Table 4-2 highlights the strengths and weaknesses of each of these individual research methods.

Table 4-2 Research methods: Strengths and weaknesses

Method	Perspective from	Purpose	Risks/ limitations
Staff interviews	NHS stakeholders	Deeper, in-depth understanding of governance issues which allowed probing and clarifications; supported a level of standardisation between interviews while allowing freedom to explore concepts	Not able to generalise. Focussed on individuals' perception when the governance processes affected multiple staff. Researcher had ability to lead or direct the conversation. Perception bias when coding transcripts. Time consuming to collect and analyse data, limited number of participants
Staff questionnaires	Sexual health nurses	Collected demographic data, opinions, and estimated costs for quantitative analysis; potential to generalise; standardised for all participants. Participants completed away from researcher.	Pre-determined by researcher enquiry, limited amount of free information participants can provide. Relied on participants returning questionnaire. High level data collection only (i.e. limited depth).
Clinical diary	Patients, nurses, NHS	Allowed real-time information to be recorded by the nurse for research purposes. Allowed data collection that was not readily available by other methods. Distributed patient questionnaires.	Participants needed to remember to complete. Accuracy affected if not completed properly. Relies on volunteers. Participants could have become fatigued. Generally used to compliment alternative data collection methods.
Clinical notes	Patients, nurses, NHS	Allowed generalisable conclusions on the provision, safety and appropriateness of medication delivery. Used validated research tools for assessment. Reduced researcher's bias.	Data were not recorded for research purposes; may not have included all aspects of the consultation. Relied on accuracy, quality and completeness of notes; locating notes was difficult at times. Involved researcher interpretation.
Observations	Patients, nurses, NHS	Provided data on interactions, communication and performance not achievable by the other methods. Used validated research tools which supported standardisation between all observations. Validated findings from other sections through triangulation.	Hawthorne effect (i.e. altered behaviour of participants being observed). Difficult for researcher to be truly non-participant. May have effected patients' ability to fully discuss their health concerns. Subtleties and non-verbal communication may have been over-looked. Observer and participant fatigue may have influenced data collection.
Patient experience	Patients	Allowed high volume of responses. Based on two validated research tools. Provided patients' opinions on their satisfaction with nurses managing their care. Researcher did not need to be present to distribute questionnaires.	Relied on suitable return rate; biased patient choice as nurses may have selectively distributed. Nurses needed to remember to distribute when medication was delivered. Took additional patients' time at the end of consultations. Limited opportunity to give detailed feedback. Potential for 'rhythm box ticking'
Costs assessment	Patients, nurses, NHS	Supported an economic evaluation of benefits to service delivery, patients and staff. Costs and consequences allowed different professionals to assess costs relating to their own specific interest.	Majority of costs based on estimations, affecting accuracy. The costs for drugs for the five sites may be different to those in the BNF due to local procurement contracts.

(Parahoo, 2006; Bowling, 2009; Moule & Goodman, 2009; Gerrish & Lacey, 2010; Creswell, 2014).

4.5 Data collection tools and study documents

The data collection tools were selected or designed/ refined by the researcher and experts in nurse prescribing, health economics, nursing research and medication safety, and through critical appraisal of existing literature. Validated tools were used where relevant to the study's objectives; these included the Medication Appropriateness Index (MAI: Hanlon *et al.,* 1992, see section 5.8.2.1 on page 146), the Satisfaction with Information about Medications Scale (SIMS: Horne *et al.,* 2001, see section 5.12.5 on page 209) and aspects of a patient experience questionnaire from Birmingham's sexual health department (Weston *et al.*, 2010, see section 5.12.5 on page 209). Following refinement by the study team, tools were piloted or sent to potential users for feedback. Further details on individual tool development, refinement, validity and reliability is presented alongside their methods, where applicable. Participant information sheets and consent forms were designed specifically for the research project; refined by the researcher, supervisor team, and the Health Research Authority approvals process. Table 4-3 details the appendices for research tools, participant information sheets and consent forms.

Table 4-3 Data collection tools and versions overview

Section	Item	Appendix
NHS stakeholders' interviews	Interview outline	Appendix A
	Staff interviews participant information sheet	Appendix B
	Staff interviews consent form	Appendix C
Staff questionnaire	Participant information sheet	Appendix D
	Staff questionnaire: independent nurse prescribers	Appendix E
	Staff questionnaire: patient group directions	Appendix F
Clinical diary	Clinical diary data collection tool	Appendix G
	Diary explanatory notes	Appendix H
	Diary participant information sheet	Appendix I
	Diary & notes review consent form	Appendix J
Clinical notes review	Data collection field list (based on Microsoft Access®)	Appendix K
Patient experience questionnaire	Patient questionnaire	Appendix L
	Patient questionnaire participant information sheet: English version	Appendix M
	Patient questionnaire participant information sheet: Welsh version	Appendix N
Observation study	Observational schedule	Appendix O
	Staff observational participant information sheet	Appendix P
	Staff observational consent form	Appendix Q
	Patient observational participant information sheet: English version	Appendix R
	Patient observational participant information sheet: Welsh version	Appendix S
	Patient observational consent form: English version	Appendix T
	Patient observational consent form: Welsh version	Appendix U
	Observational study advertising poster	Appendix V

4.6 Patient and Public Involvement

During the research design stage, eight patients, who had used a variety of healthcare services, gave their opinions with regards to the information they sought when receiving medicines. All had queries relating to medication effects and potential side effects. This is in-line with evidence presented in the empirical literature chapter, which highlighted that although nurses perceive they addressed these issues, patients often felt this was not the case. Therefore, the decision was made to observe nurse-patient interactions during medication consultations to determine the extent to which patients' concerns were addressed. These issues could not be accurately assessed through documents. Moreover, this stage also identified the need to assess patients' satisfaction with medication advice, thus supporting use of the patient experience questionnaire.

Six further sexual health patients were informally approached to obtain feedback on the draft patients' experience questionnaire. Minor modifications were made with formatting to make certain aspects clearer. Feedback also identified that the participant information sheet needed to be more concise. The suggested amendments were reasonable and incorporated.

4.7 Inclusion and exclusion criteria

The study's inclusion and exclusion criteria are presented in Table 4-4. Criteria are set out for all aspects of the study relevant to service providers, nurses and/ or patients.

Table 4-4 Inclusion and exclusion criteria

Perspective	Inclusion	Exclusion
Service providers	• Nurses used INP and/ or PGDs • NHS services that provided complex specialist management of sexual health presentations and conditions • Site provided appropriate authorisation • Easily commutable by train for the researcher from their London base.	• Support for project not achieved by local manager or Trust R&D office • Nurses did not work independently in patients' case management • No provision of a suitably trained clinician for discussion of local procedures and prescribing decisions
Nurses	• Worked in sexual health services that routinely used INP or PGDs • Voluntarily agreed to participate (except clinical notes review)	• Declined to participate in the study (except clinical notes review) • Did not use INP or PGDs
Patients	• Managed by nurses using INP or PGDs • Aged over 16 years' old • Good understanding of English • Voluntarily participated in the observational study and/ or questionnaire	• Patients attending for non-sexual health related complaint/ issue • Primarily managed by non-nursing staff (e.g. a doctor) • Patients deemed vulnerable (e.g. sexual assault, vulnerable adult/ child) or obviously uncomfortable during the consultation (observations & patient questionnaire) • Any patients who declined to participate

4.8 Study sites and settings

Study sites were purposively chosen, primarily if they employed nurses using INP and/ or PGD users in sexual health, with scope to independently manage patients' episodes. For sites to be easily commutable from the researcher's London base, cities were preferred. Cities were also regarded as having a larger pool of staff, thus facilitating the achievement of the sample quotas. Furthermore, specialist sexual health services, with the resources to manage complex presentations and conditions, tended to be city based, although many provided satellite clinics. Five sites were regarded as the maximum achievable within the project's time and resource constraints. The sites that participated in the study were situated in:

Site 1: Central London

Site 2: South Coast England

Site 3: Northern England

Site 4: Scotland

Site 5: Wales

The participating sites provided a range of highly specialist services from sexual health screening, sexual and reproductive health provision, HIV care, psychosexual services, specialist services (e.g. young people, sex workers, men who have sex with men, research, sexual dysfunction, sexual assault, 'chemsex', PEP/ PrEP) using blended walk-in and appointment services (based on clinics' websites, and orientation to departments, 2015/16). In line with expected service redevelopment to fully integrate genitourinary medicine and sexual and reproductive health services (DH, 2013), all sites were in advanced stages, or were already fully integrated. Across these services there were 95 nurses (INP=28; PGD=67) who could deliver medication independently, as presented in Table 4-5.

Table 4-5 Number of INPs and PGD users per site

Number of INP/PGD	Site 1		Site 2		Site 3		Site 4		Site 5	
	n	%	n	%	n	%	n	%	n	%
INP (n=28)	11	39.3	1	3.6	0	0.0	13	46.4	3	10.7
PGD (n=67)	18	26.9	8	11.9	10	14.9	16	23.9	15	22.4
Total (n=95)	29	30.5	9	9.5	10	10.5	29	30.5	18	18.9

INP= independent nurse prescribers; PGD= patient group directions. '%' relates to distribution of each group across the five sites.

4.9 Data analysis overview

Data were analysed using descriptive and inferential statistics using the Statistical Package for Social Sciences (SPSS) version 24.0 statistical software, Microsoft Access®, Microsoft Excel® and Nvivo version 10. Descriptive statistics present the characteristics of the sites, nurses, patients and consultations with reference to age, ethnic origin, diagnosis, medicines provided, appropriateness and safety in medication delivery and clinical practice. Data are presented, where appropriate, using the mean, standard deviation, range and frequency distribution. NHS stakeholders, nurses and patients' opinions were also presented throughout. Data analysis is presented as text, tables and charts to support the conclusions made.

The majority of quantitative data collected throughout this study involved categorical data; however, where possible inferential statistics were used to compare differences between INPs and PGD users. Statistical tests applied relied on data meeting the relevant tests' assumptions for use. The Chi Squared (χ^2) test was used to compare relationships between INPs and PGD users if each cell in the contingency tables was greater than 5, or Fisher's Exact Test if any field had less than 5 (Field, 2009). Where 'means' or 'collated mean scores' were collected, the Independent Samples t Test (t) was favoured when the sample size was over n=30, as per sampling theory (assumed equal variances used unless otherwise stated). The Mann-Whitney U test was used for smaller samples that were not normally distributed. To avoid a Type I error (false positive) the level of significance was calculated at 5% (0.05), where if the p-value is more than ($p \geq 0.05$) the results will not be considered statistically significant. Where possible large sample sizes were used to avoid a Type II error (false negative: Field, 2009). Specific analyses for individual methods are presented alongside their findings throughout Chapter 5.

4.10 Study-wide ethical considerations

4.10.1 Research Governance and approvals process

Table 4-6 details the various peer reviews and governance checks that occurred during the study. The National Institute for Health Research (NIHR)/ Health Education England (HEE) provided funding. King's College London acted as the sponsor. Research Ethics Committee (REC) Wales REC4 approval was obtained on the 28/05/2015 (Appendix W), with amendments on the 21/09/2015 (minor amendment involving clarification of data processing: Appendix X) and 21/03/2016 (substantial amendment changing source of records to be included in clinical record review: Appendix Y). The Coordinated System for gaining NHS Permission (CSP) provided initial Research & Development governance checks in August 2015 prior to obtaining local R&D approvals. The Caldecott Guardian requested clarification in the protocol, participant information sheets and consent forms on how data would be managed and stored; all clarifications were made as directed. The project was adopted by the NIHR Clinical Research Network (CRN) and the Health & Care Research Wales portfolios. Data collection commenced with 'Protocol Version 6.1'; dated 09/07/2015. This was replaced by 'Protocol Version 6.2'; dated 01/02/2016 which underwent appropriate governance authorisations to amend how the clinical notes were reviewed (see Section 5.8.2). The study passed King's College London's PhD Upgrade assessment on the 16/12/2015.

The unique ethical implications for each method are presented in the specific methods' sections. The study wide ethical issues involved are presented in Box 4.2.

Box 4.2 Study-wide ethical issues

- Data protection and storage (section 4.10.2)
- Participation of staff and patients (section 4.10.3)
- Potential of observing/ discovering unsafe practice (section 4.10.4)
- Accessing data from departments where the researcher was not employed (section 4.10.5).

Table 4-6 Governance reference numbers and dates

Approval type	Approval reference	Approval date
NIHR funding	CDRF-2013-04-052	18/11/2013
King's College London Sponsorship	None provided	12/03/2015 & 11/08/2015
Ethical (Wales REC 4)	15/WA/0120 (Appendix W; Appendix X; Appendix Y)	29/05/2015 & 21/09/2015 & 21/03/2016
NHS Site 1 Caldecott Guardian	Staff interviews: 577736	13/07/2015
	Staff questionnaires: 577873	13/07/2015
	Clinical diary and notes review: 577900	30/07/2015
	Consultation observations: 577912	30/07/2015
	Patient questionnaires: 577924	30/07/2015
NIHR CSP Study	IRAS: 148264 Study ID: 15SM2609	04/08/2015 & 11/09/2015
NIHR CRN Portfolio	19378	13/07/2015
Health & Care Research Wales	148264	22/09/2015
NHS Research & Development	Site 1: 15SM2609	01/09/2015
	Site 2: 148264/865710/6/743/279285/334156	23/10/2015
	Site 3: R04119	09/12/2015
	Site 4: 2015/0351	18/09/2015
	Site 5: 15/RPM/6281P	25/09/2015
King's College London PhD Upgrade	Student ID: 0751254	16/12/2015

NIHR= National Institute for Health Research; REC= Research Ethics Committee; NHS= National Health Service; CSP= Coordinated System for gaining NHS Permission; CRN= Clinical Research Network

4.10.2 Data protection and storage

Data protection and storage were the major considerations throughout the study. The main risks were associated with the potential breach of data protection, leading to a loss of data and/ or confidentiality. The Great Britain Data Protection Act (1998) was adhered to throughout, ensuring confidentiality of participants and legitimate access to information. The study was later registered with KCL Data Protection Register to ensure compliance with the introduction of the General Data Protection Regulation (EU, 2016) which came into effect on the 25th May 2018. Patient identifiable data did not leave NHS sites, and were only used were absolutely necessary. Identifiable data were not recorded on data collection tools, but were stored on an NHS secured server which was accessed through a secured Virtual Private Network, in line with Caldecott Guardian requirements. Hardcopy lists which detailed patient identifiable information or staff identifiers were stored in locked cabinets at each site. Authorised access to local NHS IT systems or clinical records was required to access further personal information. Demographic information collected included: ethnic origin, gender, sexual orientation, medical and sexual history, presenting complaint, diagnosis and treatment. No patients' names or addresses were recorded, other than

for the prize draw attached to the patient questionnaire (which were provided voluntarily). All references to patients or staff in this thesis are pseudonyms or study ID numbers.

In line with the university's research framework, research records will be kept for a period of 10 years on completion of the study, archived in line with KCL policy. Where possible, paperwork was scanned and stored electronically on a secure server. All appropriate hardcopies were destroyed as NHS confidential waste.

The researcher and the study supervisors met regularly to ensure high standards of data collection and analysis were maintained throughout. The study had direct health economics and statistician support to ensure rigour of quantitative data analysis.

4.10.3 Participation of staff and patients

The involvement, participation and goodwill of staff was required throughout the study. To avoid coercion, rationales for non-participation were not sought by the researcher. At all times, the voluntary nature of participation was emphasised, as was the ability to withdraw at any point without providing rationales. Written consent was required from staff prior to participating in interviews and the clinical diary, and from staff and patients for consultation observations. Two copies of the consent form were then signed, one for the participant, one for the research file. Written consent was not required for the patient or staff questionnaires, as completion and submission was deemed as implied consent. The clinical notes review was approved by the Caldecott Guardian as an audit and so individual staff or patient consent was not required.

4.10.4 Potential for observing or discovering poor practice

While undertaking data collection there was a risk of discovering or witnessing poor or unsafe practice. For all aspects of the study the researcher was to either (i) approach the nurse at an appropriate time to discuss the issue, preferably not in front of patients; or (ii) report the incident to a senior manager for further investigation and/ or training (HRA, 2016).

4.10.5 Accessing and assessing data where the researcher is not employed

Appropriate local R&D authorisations were obtained prior to accessing data sources. In areas of uncertainty relating to patient management (e.g. local policy differs from national guidelines), the researcher used local governance documents, and discussed all queries with local departmental representatives. If practice was deemed appropriate locally (e.g. followed local guidance, policies or formularies) it was recorded as appropriate.

4.10.6 Research Governance

The study was conducted in compliance with the Declaration of Helsinki (World Medical Association, 1996) and the Research Governance Framework for Health and Social Care (2005). The researcher maintained a 'Good Clinical Practice' qualification throughout the study, and complied with University and NHS Trust research guidelines. Appropriate sponsorship, ethics and local Research & Development approval was in place prior to any data collection. Amendments were made through appropriate approval channels for all protocol changes.

4.11 Defining medication errors in practice

The provision of medication is a complex process that involves a range of considerations to achieve a desired pharmacological effect in a safe, cost effective and patient focussed way. Safe medication delivery goes beyond the actual provision of medication, but also incorporates the patient's consultation, history and preferences. Safe prescribing is facilitated through accurate history taking and clinical assessment to determine medication necessity and appropriateness. Allergies and concurrent medications, including over-the-counter and herbal remedies, should be consistently checked (Latter et al., 2007a) to avoid potentially lethal or allergic reactions or drug interactions which may cause side effects, drug inactivation or toxicity (BNF, 2016). Awareness of recent medication changes may explain any new symptoms, side effects or adverse events; e.g. in sexual health antibiotic use may affect diagnostic tests or cause fungal infections (BASHH, 2016).

Accurate documentation is a key component in medication safety to provide a legal and professional record of patients' assessments and medication provision. Medication documentation should include: full details of the medication, prescribing rationale, drug name, dose, frequency and duration or review date (BNF, 2016). Prescribing decisions should be evidence based and/ or consistent with recommended practice (BASHH, 2016; FSRH, 2016). The BNF provides guidance on drug choice; unsuitable drugs; consideration of patients' comorbidities (e.g. liver or renal disease); risk associated with pregnancy and breastfeeding; adverse drug reactions and side effects; consideration of drug interactions; dose options; routes of administration; cost and monitoring recommendations (Buppurt, 2011; Wagle, 2011). The BNF (Version 70), BNF Online and Medicines Complete (https://www.medicinescomplete.com/mc/alerts/current/drug-interactions.htm) were the primary resources for assessing drug safety (for UK licensed medications). The quality of prescription writing and PGD supply were measured against the expected documentation standards in Box 4.3.

Box 4.3: Requirements of a prescription (BNF, 2016)

- Patient's details
- Name of prescribed item/ formulation
- Strength (if any)
- Dosage
- Frequency
- Quantity/ duration
- Signed and dated by prescriber or PGD user
- Given by PGD, if applicable

4.11.1 Prescribing error definition and severity

The definition of 'prescription errors' was based on Avery et al. (2012), and was used to evaluate prescription writing accuracy throughout this thesis (including PGD documentation):

> "A prescribing error occurs when, as a result of a prescribing decision or prescription-writing process, there is an unintentional, significant: reduction in the probability of treatment being timely and effective, or increase in the risk of harm when compared to generally accepted practice" (Avery et al., 2012, p. xvii).

This definition was devised through a Delphi Technique involving 35 prescribing experts, standardised over 26 alternative error definitions and provided the basis for comparisons between professionals and clinical groups (Avery et al., 2012). The term 'significant', within the definition, is intended to afford interpretation of the clinical impact of the error. This allowed flexibility to overlook minor errors that would not result in harm to patients; for example, minor misspelling of drug's names (e.g. doxycycline vs. doxcycline). The phrase 'generally accepted practice' is also important given this thesis involved five sites, across three separate countries. As local practice may have differed from national guidelines, prescriptions that were accurate locally were not considered an error, unless there was a fundamental safety issue with the local policy.

Where an error was identified, the frequency, nature and severity were assessed. Dornan et al. (2009) list of prescribing errors (see Box 4.4) initially guided the analysis of error categories, but ultimately this study generated a list relevant to its own findings. The main addition to prescribing errors in this study related to patients' past medical history, concurrent medications, allergies and pregnancy risk not being documented in the clinical records, as these are essential components in assessing medication safety and appropriateness (BNF, 2016). Moreover, missing 'administration route' in 'prescriptions' was recorded as an error, regardless of whether there was only one type of drug formulation, as this was considered good practice in prescription documentation (BNF, 2016) (excluding cryotherapy, inter-uterine devices and contraceptive implants). The severity of prescribing errors was assessed in line with a validated, reliable scoring tool (Dean and Barber, 1999) and practical application in another prescribing study (Avery et al., 2012). A visual analogue scale of 0-10 (zero means no potential effects on the patient, and 10 an error that would result in death) had a generalisability coefficient of 0.8, detailing a reliable test with construct validity for assessing prescribing error severity (Box 4.4); scores less than three are considered minor, 3 to 7 are moderate and over 7 are severe (Dean & Barber, 1999). In line with the tool, five judges (one expert research pharmacist, two consultant sexual health physicians and two experienced INPs) independently scored each error (with similar errors grouped); the mean score was the taken as the index of severity. Dean and Barber (1999) detailed that a minimum of four judges were required to make the assessments reliable and valid. The researcher approached four external judges, with the aim of obtaining three further severity assessments in addition to the researcher's, i.e. four in total. However, all four external judges

agreed to participate, therefore, five severity assessments were used in this study, surpassing the minimum requirement for reliable and valid assessments.

Box 4.4: Prescribing error categories (Dornan *et al.,* 2009)

- [*Omission on admission*]*
- Under-dose
- Overdose
- Strength/dose missing
- [*Omission on 'to take away' discharge prescriptions*]*
- Administration times incorrect/ missing
- Duplication
- Product/ formulation not specified
- Incorrect formulation
- No maximum dose documented (if an exact dose is not stated e.g. once only medicines)
- Unintentional prescription of a drug
- No signature
- Clinical contra-indication
- Incorrect route
- No indication
- [*IV instructions incorrect/ missing*]*
- Drug not prescribed but initiated
- Continuation for longer than needed
- Route missing
- Start date incorrect/ missing
- [*CD requirement incorrect/ missing*]*
- Drug interactions
- Daily dose divided incorrectly
- Significant allergy
- Continuation after adverse drug reaction(s)
- Premature discontinuation
- Drug interaction not taken into account
- No dosage alteration after levels out of range
- Dose/ rate mismatch

**not relevant to routine outpatient sexual health practice*

Error severity (Dean & Barber, 1999)
0 to <3 = Minor (very unlikely to have any adverse effects)
3 to < 7= Moderate (likely to cause some adverse effects or interfere with therapeutic goals but very unlikely to result in death or cause lasting impairment)
7 to 10 = Severe (likely to cause death or lasting impairment)

4.12 Chapter summary

This chapter has provided an overview of the research methods used in this mixed methods study designed to explore medication delivery by nurses in UK sexual health services. A description of the study's aims and objectives was presented along with justification for the research design and methods used with consideration of the relevant ethical and governance requirements. This design collected data concurrently and sequentially. Given the complexity of the methods used, and their interaction with one another, further methodological justifications are presented alongside their corresponding results in the subsequent chapters. Data are then merged in the discussion chapter structured around the study's objectives. The conclusions then specifically answer the research question with reference to: clinical application, patient experience and costs comparisons associated with INP and PGD utilisation by nurses in sexual health.

CHAPTER 5: DETAILED METHODS AND RESULTS FOR EACH TASK

5.1 Introduction

The preceding chapter, 'Chapter 4: Methods' provided an overview of the study's methods. Chapter 5 expands on this by detailing method-specific features with their corresponding findings. Given the complexity of the interactions between the multiple methods adopted, presenting the findings in this manner was determined by the researcher to provide the greatest clarity and ease of reference, as agreed by study supervisors. The first topic is the staff interviews, which are followed by staff questionnaires, clinical diary, patient experience questionnaire, clinical notes review, observations of medication consultations and the cost & consequences. The findings from the individual methods are triangulated throughout the discussion chapter.

5.2 Staff interviews: Task-specific methods

5.2.1 Purpose

Senior NHS stakeholder staff interviews facilitated a qualitative explanatory basis to the study. The interviews allowed the researcher to explore nursing leads' perceptions on the strength and weaknesses of nurses' independent delivery of medication, as well as the local governance and training processes. The interviews facilitated a deeper understanding of local practice(s) of how each site managed and used INP and/ or PGDs in clinical practice.

5.2.2 Method design

Face-to-face semi-structured interviews used open-ended questions to elicit a dialogue with participants. Further exploration of concepts raised during interviews then expanded on

participants' opinions of local governance, training, and the benefits and barriers to nurses independently delivering medication from an organisational perspective. The use of a semi-structured interview schedule enabled topic standardisation between all five participants while allowing flexibility in exploring individuals' experiences and perceptions. This design provided the researcher the opportunity to clarify or expand on ideas raised (Moule and Goodman, 2009). The interview schedule, which was created based on the review of existing evidence and discussions between the study's supervisors, is presented in Appendix A.

5.2.3 Recruitment

One senior NHS stakeholder from each site (n=5), with overall sexual health governance responsibility for INP and/ or PGDs, was invited to participate in an audio-recorded interview. During the formative stages of the project, the researcher approached five sexual health services to organise departmental participation based on the site inclusion criteria (see page 92). The researcher subsequently liaised with five senior nurses to obtain the necessary research governance approvals for each department. These senior nurses also identified themselves as having overall INP and/ or PGD governance responsibility for their service, and were subsequently invited to be interviewed.

Participants were given a copy of the participant information sheet (Appendix B) and consent form (Appendix C) at least 48 hours prior to the interview. The voluntary nature of participation was highlighted, and an opportunity to ask questions was provided prior asking participants to sign the consent forms.

5.2.4 Data collection

Interviews were conducted in participants' offices at times suggested by themselves to reduce the impact participation would have on their work routine. The researcher endeavoured to probe only on issues specifically raised by the participants to avoid leading the interview. Open ended questions and confirmation statements were used to corroborate understanding of concepts raised. All data protection and governance processes presented in Chapter 4 were adhered to.

5.2.5 Analysis

Audio recordings were transcribed verbatim and thematically analysed. References to specific people or sites were anonymised. Hardcopies of interview transcripts and NVivo 10 were used to support inductive analysis of the interview data. Transcripts were thematically analysed using codes that appropriately defined the data's content. Codes were linked to create overarching themes. This process was undertaken across six stages, as described by Braun & Clarke (2006). The stages are shown in Table 5-1.

Table 5-1 Stages of thematic analysis undertaken

Stage	Phase	Analysis (for this study)
1	Familiarising yourself with the data	The researcher listened to all the interviews and read the transcripts through. Transcripts were re-read and initial notes made
2	Generating initial codes	Transcripts were transferred into Nvivo (v.10), and each line/ subject/ topic was coded
3	Searching for themes	The codes were reviewed and gathered to determine emerging themes
4	Reviewing themes	The coded extracts, initial notes and transcripts were re-reviewed to determine validity of the draft themes
5	Defining and naming themes	Themes and subthemes were refined into clear constructs
6	Producing the report	The findings were written focusing on how the transcripts addressed the research question/ objectives (see page 83)

Adapted from Braun & Clarke (2006, page 87)

To support methodological rigour, processes to enhance credibility, transferability and dependability were employed throughout data design, collection and analysis (Endacott, 2008). All three aspects were enhanced through supervisor support and feedback throughout the various research stages. Credibility was increased as each participant reviewed their transcript prior to analysis to ensure it accurately reflected their interviews and individual opinions. All participants agreed they did. One participant requested that a single phrase was removed from their transcript. While the clinical setting of the interviews was restricted to sexual health, the concepts and themes raised are transferable to other clinical areas given INP and PGDs are governed at organisational and national levels. According to Creswell (2014), transferability of evidence is achieved through rich, thick descriptions. As such, each theme and subtheme is confirmed using participants' quotations. Dependability was enhanced by using Braun & Clarke's (2008) stages of

thematic analysis, as presented in Table 5-1, which provided a clear framework for data analysis and formation of themes. An example of transcript coding is presented in Appendix W.

Reflexivity is an essential consideration during analysis of qualitative data (Creswell, 2014; Ritchie *et al.*, 2013). For transparency purposes, the researcher discloses that they are a senior sexual health nurse with personal experience of INP and PGD governance and training. Having personal experience inevitably influenced the questions posed, probing during the interviews and how data were subsequently analysed (Ritchie *et al.,* 2013; Tufford & Newman, 2010). While the researcher made efforts to ensure inductive interview questioning and analysis, it was inevitable their experience influenced this process, perhaps even enhanced a deeper line of enquiry and analysis. However, use of the aforementioned process helped ensure themes were derived directly from the data and not the researcher's personal opinion.

5.3 Staff interviews: Findings

5.3.1 Coding

Four sites used both INP and PGDs, and one site only used PGDs. All participants were lead nurses in the sexual health department. Demographics were not collected to protect participants' anonymity. While all five provided overall responsibility for INP and/ or PGD governance, two had more extensive experience of integrating and managing the introduction and maintenance of both medication delivery methods. A total of 76 initial codes were generated across the five interview transcripts. Table 5-2 provides a summary of each interviews' duration and number of initial and total codes that emerged during analysis.

Table 5-2 Length and code details of staff interviews

Participant ID	Duration of interview (mins)	Number of initial unique codes identified per interview	Total number of codes per interview
P.1	46m	56	415
P.2	20m	43	254
P.3	18m	40	201
P.4	63m	46	753
P.5	20m	54	262

P.= participant

5.3.2 Overview of themes

The findings are discussed under three main themes: 'clinical governance', 'service delivery' and 'training and resources'. Several sub-themes are explored within each themes, as presented in Table 5-3. Key points are illustrated using anonymised quotations from participants (P.).

Table 5-3 Overview of themes for stakeholder interviews

Themes	Sub-themes
Clinical governance	• Advancing nursing practice with access to medication • Defining advanced practice • The influence of banding on clinical practice • Accessing medication: INP formularies • Accessing medication: creating and maintaining PGDs • PGD use in clinical practice
Service delivery	• Efficiency of service delivery • Provision of nurse-delivered clinics
Training and resources	• INP training • INP training resources • PGD training • PGD training resources

INP= independent nurse prescriber; PGD=patient group directions

5.3.3 Theme 1: Clinical governance

The 'clinical governance' theme emerged from all interviews. There was a strong sense of how nurses' roles, medication legislation and clinical standards were applied to support medication delivery in practice. Participants highlighted how medication legislation had facilitated advanced practice for sexual health nurses; however, clear differences in clinical application were evident in terms of which medications were available and how these were accessed.

5.3.3.1 **Advancing nursing practice with access to medication**

All participants discussed advancing nursing practice and how the role of the sexual health nurse had evolved. As practice shifted towards increased autonomy, the nurses' interaction with doctors had also changed:

> "When I first came here, we were doctors' handmaidens, so to speak. So…the equivalent of say Band 6 nurses, chaperoned doctors, passing swabs to doctors, getting clinics ready for doctors. And then perhaps just doing wart treatments following a prescription written by a doctor." P.5

> "nurses now deal with patients who have got infection, who are symptomatic, who have a wide range of infections, it's not just the domain of the doctor...So they [nurses] can get on and treat without necessarily seeing a doctor." P.4

Nurses' access to medication was a key component in facilitating advanced practice. When asked how important access to medication was for nurses' roles, one participant responded:

> "its fundamental, is completely fundamental to the role" P.1

As the governance for accessing medication evolved, so did nurses' scope of practice. One participant recalled that prior to the introduction of PGDs, there were difficulties accessing medication, even when patients could purchase certain items from pharmacy:

> "when I first came here, nurses couldn't use any PGDs or prescribe or give any medication. And it was really difficult because you were constantly chasing after doctors, even asking for a prescription for something like a Canesten pessary, which you can buy over a counter." P.5

Recalling practice prior to PGD introduction also raised questions from participants, related to the

governance surrounding doctors prescribing medications for patients managed by nurses, or from nurses using local medication 'protocols':

> "So, "I've seen the patient, I assess them, I think this is what they need, would you mind prescribing it?" And because the doctors knew us and trusted us, they would often say 'yes' without seeing the patient, you know. And, so although you tried your hardest to build in good governance around that, it wasn't robust." P.4

> "We've had nurse practitioners working in sexual health here since 1996. And I started here in 97, and we had group protocols within which we used to issue medication, but we subsequently discovered that legality of those may or may not have completely ideal. And that led on to obviously PGDs and then on to non-medical prescribing." P.1

The introduction of PGDs was, therefore, regarded as an advancement in terms of service delivery for patients and for safe clinical practice:

> "I think PGDs are, are hugely useful. And before we had prescribing, we just thought they were amazing because it was the first time that we'd had the freedom to complete an episode of care for a patient and to feel that we'd done that safely." P.4

The introduction of INP was seen as another significant milestone in advancing nursing practice in terms of governance and flexibility:

> "once those ones who had become prescribers began to put that [INP] into practice, we realised just how cumbersome the PGDs can be" P.4

> "I think for me personally it's the thing [INP] that has completely opened up practice" P.1

INP's flexibility in clinical practice was highlighted by all participants. Two participants discussed the impact INP had on the management of persistent genital warts:

> "I've got my own, run my own treatment where it's mainly patients with genital warts. And they send me complex patients where – because when we treat genital warts, we tend to follow a guideline or a protocol on what the best treatment is for the different types of warts; whereas, when I see them, I can work a little bit outside the box, a little bit outside the protocol." P.5

However, not all participants agreed that INP was currently appropriate for their services. One participant highlighted PGDs were fully established within their service and were appropriate for nurses' current practice. Nevertheless, it was acknowledged the benefits INP would bring for more advanced scope of nursing practice:

> "we started with PGDs and that works fine. And nobody is coming forward saying that they want to be a non-medical prescriber…There is no need. You know, if it's not broken, why try and fix it, because it's [PGDs] working really well" P.3

> "it's a drawback of our service and our nursing team and it's something that I'm really mindful of and I want to promote, is more advanced nurse practitioners… I think that we should have more expertise in our sexual health nurses and have more advanced nurse practitioners, and that goes hand-in-hand maybe with non-medical prescribing." P.3

From an individual nurses' perspective, it was highlighted that some nurses were content using PGDs, if they covered the required clinical presentations:

> "the majority of staff find, especially if we're getting these treatments, like the gonorrhoea treatment on PGD, I think they find that's enough for them" P.5

5.3.3.2 Defining advanced practice

Defining the concept of 'advanced practice' was raised. One participant felt this was a loosely defined term and needed to encompass a specific level of practice, academic achievement, incorporate INP and be formed around competency based assessment frameworks:

> "I personally feel that we should have system like in America, where you have to do a nurse practitioner course, that it's a second registration…and depending on what area or field of practice, that you do placements and you have assignments and that non-medical prescribing should be part of that." P.1

> "non-medical prescribing…needs to be seen within an educational framework, that is both broad in terms of…physical assessment, but specific in terms of discipline…because I am a complete advocate for advanced practice, I think it needs to be within a Masters framework. And I say 'framework' as opposed to a Master's degree because I think that different people, different specialities…will have different requirements for that, but I definitely think they should fit within, the national competencies for advanced practice" P.1

While the achievement of such an academic standard was seen as desirable, it was acknowledged that this may not always be practical due to an individuals' inability to study at the required level or, because of the resources required to obtain it:

> "We do want all our specialty nurse practitioners to get a degree, but it's quite a big thing especially if you didn't qualify, if you qualified back in the eighties or nineties. And they're not perhaps very academic." P.5

> "There is a course they have to do [for INP]. And it's expensive and it's time-consuming and you have to write a huge piece of work for it. Those who are academic don't mind that. Those who are not absolutely hate it." P.4

5.3.3.3 The influence of banding on clinical practice

Nurses' banding was seen as an indication of their expected scope of practice. Three participants aligned banding with an expected level of skill, clinical competence and access to medication:

> "Band 5 nurses…they're trained in their kind of foundation competences in sexual health, and the next thing we feel that they would benefit, and patients would benefit, and clinic would benefit from, is those Band 5 nurses having some access to some of the PGDs. A 6 will see symptomatic patients independently. A 5 basically won't see symptomatic patients independently, but will do everything else. They'll do treatments, nurse follow-up, cryotherapy, asymptomatic, complex asymptomatic, partner notification. They will do everything else apart from independently see symptomatic patients." P.3

Participants consistently identified that Band 5 nurses should have access to PGDs, and some highlighted that PGDs were useful clinical training tools:

> "I think the PGDs are very targeted, so that's quite useful for our junior staff, because it means that they can concentrate on learning one thing, like Hepatitis B vaccination; as opposed to having to learn the whole thing" P.1

The clinical expectation of specific bands was raised by one participant in relation to a lack of PGD competence, despite their band:

> "She came to us as a trainee, as a Band 5, and was promoted to a Band 6, it's probably at least a year, which is why I'm so surprised that she hasn't yet got that [PGD sign-off]." P.3

While participants agreed Band 5 nurses should be able to use PGDs, there wasn't the same agreement with regards to INP banding, or the level of 'coercion' to complete INP training. One participant felt INP should be voluntarily introduced at Band 6, whereas another respondent was of the view that it should be expected, and protected, at a Band 7 nurse practitioner role:

> "we regularly identify who needs, who's next to go on the prescribing course. And nobody is coerced on to it. So we tend to, our aim is to have all our Band 6s and above prescribing." P.4

> "once you start as a nurse practitioner the first thing we are going to put you on, before your little feet touch the ground, is the non-medical prescribing course." P.1

> "there is a thing about delineating practice between what a junior nurse can do and what a senior nurse can do; because it is the only way that we can then protect our senior nurses, because the junior nurses at some point will want to go into a Band 7, and if we've eroded that, then there will be no Band 7's for them to go to" P.1

5.3.3.4 Accessing medication: INP formularies

The four participants utilising INP discussed their formularies (i.e. locally/ nationally approved

drugs available to practitioners). INPs' access to medication varied across different services. Two services had a clinic formulary that met nurses' requirements for accessing medication, while another had the full range of medicines listed in the BNF:

> "We've got a clinic formulary. We've got a second formulary, but I tend to stick to the drugs that we've got in our clinic. I don't think I've ever prescribed anything that isn't a drug that's one of our formulary drugs." P.5

> "we have been very clear about not having a very tight formulary, so I know that historically within the Trust they've wanted to have like a really, really tight formulary saying that non-medical prescribers can prescribe A or B or C. And we resisted that and kept it quite broad…And as our old Director of Nursing said, 'we have a formulary for non-medical prescribers, it's called the BNF'" P.1

The fourth service required individual nurses to keep a personal portfolio of specific drugs they could prescribe. Interpretation of legislation was the rationale for creating these formulary portfolios. The arduous nature of this was likened to individual nurses writing their own PGDs:

> "our understanding is from our training is that each of us should have our own core formulary. And that's something that we can add to as we go along…we all had this core formulary that we did ourselves. And we did it pretty much off the back of the course." P.4

> "so I would just go into my folder, get up a template and work through that, get all the information I need to fill that in. It's a bit like writing a PGD." P.4

'Intention to practice' forms (locally derived documents outlining drugs that practitioners intend to prescribe) were used by one service to determine the range of drugs INPs could access. The intention to practice forms made INP governance more straightforward, dynamic to change and manageable in comparison to the personal portfolios:

> "[For the] intention to practice form…I've created a blurb that gives enough detail of what we would expect our nurses to prescribe, without having to list every single medication. Which means if there is slight change then that can be incorporated quite easily because you would just change your practice….some people list every single medication in the way that they would with the PGD. For us, 'cause the practice changes quite a lot, that would be a complete pain…to actually administer. Because it would mean that I'd have to ensure that every…independent prescriber updates their forms if there's a change in practice, and I haven't got time for that" P.1

The intensity and volume of work to create personal formulary portfolios in P.4's service resulted in some INP reverting to PGDs to deliver medication. However, the concept of INP using PGDs was not seen as beneficial, or required by another participant

> "there were a couple of prescribers…and they were talking about PGDs that they use and I was saying, "Oh you use that PGD." "Oh yes I do…because I haven't got it in my formulary. So, and

> I know I should get it into my formulary and I will one day, but I haven't yet, so I just use the PGD." And because the PGD is there, I suspect it means they never get it in their formulary because it's just too easy to use the PGD." P.4

> "So I've never given anything under PGD since qualifying as a non-medical prescriber, because I just don't, I don't really see the advantage of doing that." P.2

5.3.3.5 Accessing medication: creating and maintaining PGDs

Three participants had direct involvement in creating, authorising and maintaining PGDs within their services. They were also members of their Trust's Non-Medical Prescribing Committees. These three participants frequently used the terms (or variations of): "challenging", "the problem", "long", "cumbersome", "time", "pain" and "complexity" to describe PGDs. The complex authorisation processes were discussed by participants:

> "we've just added wart treatments to the PGD, and then that had to…be disseminated locally for all of the medical consultants to comment on, then it had to go to our nurses meeting, it had to go to the local GU meeting, it had to go to the directorate meeting, it had to be signed off by a divisional director of nursing, it had to be signed off by the chief principal pharmacist, it has to go to the non-medical prescribing, because it has antibiotics it has to go to the drugs and therapeutics committee. So it's just so long, and difficult to get people…first of all to even read the frigging thing" P.1

> "the initial work was fairly laborious in that, in getting the right template, getting it all written, getting it to the right committees by the right time. If you missed the deadline, you waited another month until it went to the next committee. And, of course, having the pharmacists rewrite what you've written, it meant that, you know, from the thought of having a PGD, to actually having it in place, was probably something like six months." P.4

> "we'd have a lead clinician…get that signed, the pharmacists sign it. So it gets batted around in the internal mail until it's all completely signed off. Once that's done, it's then put up on to the intranet, it goes live, it goes public, and then it's sent back to us with that signing sheet photocopied and, and at that point, we tell our staff, "We've got this new PGD, or this updated PGD." We have folders in various strategic places around the clinic, and all the nurses are told, "You need to sign for that new PGD." So that takes a little time. We have nurses working who only work out in satellite clinics. And we used to send the PGD, we still do actually if they are really remote, we send the PGD out to them and say, "You sign that and you keep that in your own place of work." But the central staff, we just have one copy here and everyone signs it here." P.4

Because of the protracted PGD approval process it was highlighted that PGDs were not as dynamic as INP to changes in practice or to the availability of new medications:

> "one of the big issues with PGDs…there's a time lag. So if something changes in practice, you can change your individual practice, but in terms of actually issuing medication, you have to wait until the PGD has been re-ratified through that whole process." P.1

The chair of the non-medical prescribing committee was a key component for the efficiency of the approval process:

> "So I think that when a new chair came in, she inherited a bit of…a kind of mess, if I'm honest, with regards to PGD. So there didn't really seem to be much understanding of which PGDs were being used where and this kind of thing. And it's taken her a while to kind of get the house in order. And I think that she's just very organised and efficient and works with a team of people who are also organised and efficient and have a real will to enable people to use PGDs safely in the organisation." P.2

The requirement for each drug to be presented in its own PGD document, and for each document to have to undergo a revalidation process added further frustration for participants:

> "I can't remember how many we have. But probably twenty or something, possibly more. And they've been developed by different people at different times. So they come up for review at different times...And so it's just a bigger bit of work because of the sheer complexity of the number." P.4

> "continual process of renewal. So every two years, they have to be re-validated, which means after the first year you then have to complete all the audits…and you have to do start that process, so that when it runs out in two years, the next one is ready to go, which is a logistical pain" P.1

While overall participants thought PGDs were useful, some participants questioned whether the effort was worth the outcome:

> "[PGDs are]... incredibly useful. But the amount of time it takes is disproportionate" P.1

To make the process simpler participants discussed the benefits of a suite of PGDs, rather than individual documents. A suite of PGDs combines similar drugs under a single PGD document, rather than individual documents for each drug. The ability to use PGD suites varied between sites: one site was already using them, another was in the process of approving them, but were completely rejected by a third:

> "I think we're going to have one suite of PGDs, and I think that the reason for that, is that our colleagues have been able to demonstrate that this is custom and practice in other areas...in my NHS Trust, we have a very, very pragmatic chair of the PGD group." P.2

> "I sat and combined them all, got this lovely one-size-fits-all PGD, and then it's thrown back at me." P.4

In stark contrast, interviewees were much more appreciative of PGDs' governance when the task was delegated to colleagues:

> "I delegated that [laughter]…It was really easy…one of the Band 8As actually was responsible for adding those parts. And they went off and got all of the information, and put into the format for the monograph…So for me it was quite straightforward, cause I just needed to review what they had written." P.1

> "one person took the lead, got it done, it was their pain, not ours. And we just said, "Oh great we've got another one," when it duly arrived and we signed for it." P.4

Moreover, where the PGD governance role was managed by a pharmacist, lead nurse participants were much less critical, one found it almost pleasant:

> "we gave her a list of what we wanted. I think she wrote them and then had to get it signed off by the chief pharmacist, the – possibly the chief executive and somebody else senior – a few senior people had to sign them off – medical director, I think, before we could start using them" P.5

> "And it all went through quite quickly [PGD approval process]. And, for me, it's quite, it's a very nice process because it happens around me very efficiently. And people just seem to know what they're doing and get it done." P.3

5.3.3.6 PGD use in clinical practice

While all participants agreed that PGDs were beneficial within clinical practice, their restrictive nature was discussed. The main restrictions related to: PGDs' lack of clinical flexibility; nurses inadvertently overlooking treatment exclusions; and the need to obtain doctors' prescriptions for drugs covered by outdated PGD documents:

> "PGDs are fine to a point, but there are limits with the PGDs in, you know, in that you can only give it out in a particular situation with a particular type of patient" P.1

> "There are little funny exclusions sometimes that people just forget about." P.4

> "One thing is Ceftriaxone for the treatment of gonorrhoea. The reason it's not [available as a PGD] is when our PGDs were written, ceftriaxone wasn't a treatment for gonorrhoea. So they are still constantly trying to find somebody to write that [a prescription] for them, which I feel could be on PGD really" P.5

PGDs also created unnecessary differences in clinical practice between INP and PGDs. Despite certain PGD nurses having advanced contraception skills (e.g. intra-uterine coil insertions), they were limited to providing just three months pill supply; whereas INP could provide up to five years. This ultimately affected patients' interactions with the service:

> "in our community clinics, where we've giving contraception, there was a barrier to PGDs. We can only prescribe three months' worth of contraception to each patient, whereas with independent prescribing, we can write up a prescription which will last five years. And the patient just comes back in and gets reviewed once a year. So a nurse prescriber, independent prescriber, could do that. But the staff using PGDs can't. So it does mean more visits for the patients to see somebody that's using PGDs." P.5

In sites where INP was used in clinical practice, the participants all agreed that INP removed these inherent PGD restrictions:

> "some of us have done nurse prescribing, which…helps even more because we're not stuck to strict protocols." P.5

5.3.4 Theme 2: Service Delivery

The impact INP and PGDs had on service delivery was another strong theme that emerged from interviews. This theme explores the impact nurses access to medication had on how services could be delivered, and the noticeable effect when nurses couldn't practice autonomously.

5.3.4.1 Efficiency of service delivery

All participants used the term 'efficient' with regards to independent access to medication and its impact on service delivery. This ultimately allowed increased capacity and improved patient journeys:

> "I think that our services are very positively affected. I think that it's a much more efficient pathway for the journey, pathway for the patient if they're not having to wait around for a doctor to prescribe for them, when they've had an episode of care completed by a nurse" P.2

> "So we're able to see these extra patients now. If we'd stuck as we were in 1999, we would not be getting through the patients, the sheer number of patients we're getting through now, because we'd have to have a doctor there, we wouldn't be able to see so many patients." P.5

Several personal/ professional benefits were also expressed by participants beyond the efficiency of service delivery. These included increased satisfaction for both patients and staff, and greater holistic care, i.e. nurses were enabled to deliver complete episodes of care:

> "I like the efficiency of it, I couldn't stand…having to wait for someone, used to drive me mad, you know, you'd have a pile of notes and you'd think, "There's all these people to see, and here I am standing here waiting for a doctor."" P.4

> "I think that it's really improved the patient journey and the patient satisfaction and I think it's also improved staff morale and just kind of given people more of a sense of pride around their own work when they're able to complete a whole episode of care." P.2

> "It makes the patient experience better because of not seeing different clinicians and nurses and having to disappear to get prescriptions" P.3

In circumstances where medication access was not available this had a noticeable impact on service delivery. Frustration was evident not only from nurses seeking prescriptions, but also from the doctors being asked to sign them. This was subsequently seen to affect service efficiency and

productivity:

> "they're [Practice nurses] having to go and ask for a GP to prescribe this drug which just is another step for them, but it's quite a laborious step." P.4

> "Those doctors will get to know which nurses aren't able to use PGDs and those are the doctors who will come back to me and say, "Oh such and such can't do it, it's slowing things down and it's not as effective, it's not as efficient," you know, it's taking up their time. So I get complaints maybe from doctors in terms of efficiencies." P.3

5.3.4.2 Provision of nurse-delivered clinics

Nurses' independently accessing medication was described as facilitating the growth of nurse-delivered clinics, in both main service hubs and satellite/ outreach services. The ability to provide medication was seen as creating a more flexible approach to how services could be provided:

> "It just makes it run a much more flexible service delivery, you know, people can multitask and they can be put anywhere almost" P.4

> "now we've got nurses running clinics without doctors even being there, and making autonomous decisions for the care of patients." P.5

Participants highlighted that as nurses' ability to provide medication had increased, so had the expectation to manage more complex patient presentations. The integration of genitourinary and contraception specialities has created additional complexity to consultations, as historically these were distinct specialities. Moreover, patients were seen to be presenting with more complicated pre-existing health issues:

> "so we are seeing more patients for integrated appointments now than prior to integration. So people needing sexual health care, sexual health screening and contraception. And that might be what people come for, but it might [also] be a bit of an incidental finding when we take people's histories." P.2

> "maybe there's a temptation in sexual health to think that patients are young and well. And actually that's not necessarily the case. In my area we have a growing population of people living with HIV for much longer. So, you know, they may be on lots of, you know, they've got poly-pharmacy, they've got chronic conditions that they're living with, so actually this idea that people that come to sexual health clinics are really well and uncomplicated, I think is not necessarily the case." P.2

As nurses' roles and expectation of autonomous practice had increased to manage more complex cases, the benefits and flexibility INP brings over PGDs was highlighted. This was particularly evident in satellite clinics and outreach services where PGDs were regarded as much less practical:

> "We do a lot of satellite clinics, peripheral local clinics and I think most of us who work in those, are prescribers. And we couldn't really do it otherwise, because so many of our patients wouldn't fit the PGD criteria." P.4

> "I also work in a prison. And in the prison I can use different drugs for patients I see there, that might be not, that we might not have on PGD." P.5

5.3.5 Theme 3: Training and resources

Issues surrounding training and the resources required for training was the third key theme that was elicited from participants. This theme highlighted that while the provision of INP training was relatively consistent, there were vast differences in how PGD training was provided.

5.3.5.1 INP training

In the four services that applied INP, the predominant feature with regards to INP training was the difficulty of the course. The depth of knowledge acquired during the INP course was significant, but viewed as worthwhile. However, the level of academic assessment was regarded as higher than Master's level study, even when taken at degree level:

> "I think that, for me, it's been an incredibly positive thing. I think that my understanding of pharmacology and issues around diagnosis and management have just improved enormously since undertaking the course. The course is really challenging and it's the hardest thing I've ever done, ever!" P.2

> "it was…delivered at [degree level], with the option to do it at Masters level…But I did it at [degree level], because I already had a masters and I thought it was incredibly high level…I thought it was way beyond, assessed well beyond [degree level]" P.4

Nevertheless, from a managerial perspective, assessment at such a high level was reported to produce safe nurse prescribers. This subsequently provided confidence for managers that individual nurses were competent to undertake the INP role. However, from an individual nurse's perspective, the difficulty of the course was often seen as a barrier to undertake INP training:

> "In terms of non-medical prescribers, I mean it's a very robust course anyway, you know, in terms of all their written assessments and their portfolio, and their exams and short answer papers and maths questions, so because of that I'm quite confident that once been through that, and that they have passed that they're okay" P.1

> "I think a big barrier to them doing the prescribing course is the amount of work involved. I think we've all come back, those of us that have done it, we've all come back and said about how much work is involved and possibly, unfortunately, put some of them off." P.5

Consistently, INPs across the four sites, were all very clear that the medical team were extremely supportive. Doctors were seen to be supportive as INP had an immediate impact on the service and their interaction with nurses:

> "my designated medical practitioner in the team was just very supportive, you know, he's worked with non-medical prescribers before and I think, you know, he totally saw the value of members of the team who have got, you know, a degree of sexual health knowledge and skill and are managing, you know, starting to manage more complex needs and that kind of thing, I think he really saw the advantage of it." P.2

> "it was only very small numbers of us that were doing it, and they could see the immediate benefit, because they were fed up being asked continually to prescribe" P.4

5.3.5.2 INP training resources

A predominant resource issue with INP training was the funding, length of the programme and time required for the university course. While INP funding was previously readily available, NHS education funding budgets had been reduced. This created uncertainty amongst participants with regards to whether the courses would be funded in the future. Nevertheless, costs associated with INP training were viewed as a worthwhile, cost-effective investment; particularly with regards to the flexibility INP provided compared to PGDs:

> "funding for non-medical prescribing courses comes separately, currently. I think that the amount of education budget that the Trust is going to get in the next financial year is going to be significantly reduced." P.2

> "the current costs I think is £2,000 for non-medical prescribing at [university],…and actually it creates an incredibly robust practitioner at the end of it, and I think that's a very small investment for that. And it means we don't have to worry in terms of the minutia of if something changes, or if you change from one brand to another do we have to update the PGD, we don't have to worry about any of that." P.1

In addition to costs, participants reported that nurses were taken out of clinical practice for 26 days to complete mandatory university training. This was seen as a difficult resource to accommodate. While some services attempted to give the full 26 study days, others had already cut the number provided:

> "I'd be very keen to support people with a hundred percent study time for attending study days." P.2

> "I had a full hundred percent study leave. I think now it's probably fifty percent study leave." P.5

Participants recognised that to complete INP training, nurses had to invest far more than the 26 university study days. Given the degree of personal commitment and amount of expected

knowledge acquisition, participants were keen to preserve the 26 study days as far as possible, particularly as nurses must complete a substantial proportion of INP training in their personal time:

> "The 26 study days is a challenge, but we work to that because we expect nurses in their 26 days to gain an inordinate amount of knowledge, that medical students probably take two or three years to assimilate. So I think the 26 study days is completely fair." P.1

> "The hundreds of hours that you will do will not all be given to you within your contracted hours. It is a bit of a partnership really" P.2

5.3.5.3 PGD training

In comparison to the standardised national curriculum for INP, training for PGDs was reported to be inconsistent across the five sites. The level of pharmacology knowledge was considered superficial, in comparison to that provided on INP programmes. Yet despite the limited medication knowledge junior nurses could independently provide medication:

> "The problem is they don't necessarily get any in-depth pharmacology, pharmacokinetics, pharmacodynamics in relation to administering those. So the most junior people are administering medication, and we assess them robustly in terms of making sure they are safe and effective in what they do, but they don't necessarily have the theoretical underpinnings for that" P.1

Throughout individual interviews it became apparent that PGD training and assessment processes varied greatly across services. Table 5-4 summaries these vast differences, highlighted in interviews, in training and assessment by individual sites to achieve and determine PGD competence.

Table 5-4 PGD competency assessments as reported during interviews

Type of training/ assessment	P.1	P.2	P.3	P.4	P.5	Total
Competency based assessment	✓	✓	✓	✓		4
Tutorials	✓			✓	✓	3
Observed practice	✓	✓	✓			3
One to one discussions		✓	✓		✓	3
Group meetings		✓		✓	✓	3
e-learning (PGD specific)		✓	✓			2
Self-directed study	✓	✓				2
Auditing of notes	✓					1
e-learning (general)	✓					1
Observed Structured Clinical Examination	✓					1
Reflections	✓					1
Examination	✓					1
Assigned mentor		✓				1
University courses (e.g. contraception)				✓		1
No formalised training					✓	1

P.= participant

Participants reported that most sites utilised competency based assessment for PGD training; however, there was great variation in how this was undertaken. One service provided PGD training alongside asymptomatic screening assessments, integrating the ability to provide medication alongside clinical competence. Whereas another site had no formalised process for PGD training in place:

> "so when they do their clinical', they do a week of clinical practice, 'when they do the clinicals that at the end of that they're signed off on their PGDs so that they're hit the ground running, and it's not something we have to think about afterwards'" P.1

> "usually a new member of staff coming to us, that's going to be using them, has already trained, has done a course already to be able to work here and already knows the drugs anyway. But we just make sure that they know the side effects and things like that. But, and we go through the PGD, but they don't actually have formal training now." P.5

5.3.5.4 PGD training resources

'Time' was highlighted as the primary PGD training resource, but this was an extremely limited resource. Finding time varied from: difficulty having time to spare clinical staff to undergo training because of low staffing numbers; to trainers being busy with other components of their roles; or not having enough staff that require training to justify the trainer's time:

> "I think that we're in a situation at the moment where the clinic is very short-staffed. So freeing staff up or being able to work alongside staff to support them in becoming confident and competent with more PGDs, is very challenging." P.2

> "most of my kind of stress around PGDs actually is self-engendered because I'm busy and I don't get it done, it's done piecemeal rather than all done at once. It's not anybody's fault, it's just busy-ness." P.4

> "The pharmacist is so busy, she wouldn't want to run a session just for one person. So we have to make it worthwhile really." P.5

Another participant highlighted that if the importance of PGDs on service delivery was better understood at strategic levels, then additional resources may be made available to support training:

> "I think that maybe an increased awareness across the organisation of why we use PGDs, how we use them, how it improves the patient care, would be really helpful. And I guess that's up to us as people working within the speciality to do that, isn't it? And I think that maybe by affording PGDs and settings like this, with a higher profile, it may mean that we get more resources to do it" P.2

In contrast to considering the cost-effectiveness of the resources required for INP training, one participant was much less confident on the cost-effectiveness of the PGDs. They identified the opportunity costs associated with PGD creation, training, assessment and maintenance could be better allocated:

> "I'm not sure if [PGDs] are cost-effective. If you think about that every department…has to go through this process. That's a lot of senior nurse time that could be spent with patients, or training staff, or doing research or other stuff" P.1

5.3.6 Staff interviews summary

Participants consistently agreed that access to medication was fundamental for nurses to undertake their clinical roles. The integration of PGDs and INP was reported to have facilitated sexual health nurses to evolve from doctor's 'handmaidens' to autonomous practitioners, able to provide complete episodes of safe, legal care. Service efficiency and accessibility, improved patients' experience, and expanded nurses' roles (which increased job satisfaction and career prospects) were all seen to be benefits that arose from independent access to medication by nurses.

Nevertheless, there was a clear divide in how participants viewed INP and PGDs. From a stakeholder's perspective, PGDs, although essential, were mostly regarded as 'cumbersome', 'restrictive' and 'painful' to govern and use in clinical practice. In all services where INP was

applied, participants were clearly more favourable towards INP, as compared to PGDs, in terms of flexibility, robustness of training and benefits to service delivery.

5.4 Staff questionnaires: Task-specific methods

5.4.1 Purpose

The staff questionnaire explored the demographics of sexual health nurses who were independently delivering medication at the participating sites; nurses' attitudes on how this impacted on their practice; and their awareness/ recall of resource implications. Distribution of the questionnaires also provided an opportunity to introduce the entire study to potential participants to support recruitment for subsequent stages.

5.4.2 Method design

Questionnaires are an economical and easily administrable method for collecting quantitative data (Moule & Goodman, 2009). The two questionnaires (INP and PGD versions) were designed specifically for the study based on existing nurse prescribing questionnaires and evidence presented in the 'Background', and 'Review of Empirical Evidence' chapters. The questionnaires were split into three distinct sections: background (demographics); views on independent medication delivery; and about becoming an INP/ PGD user. Relevant comparable background/ demographical data were predominantly based on existing questionnaires by prominent UK nurse prescribing researchers (Courtenay & Gordon, 2009; Courtenay & Carey, 2008; Courtenay *et al.*, 2007a; Courtenay *et al.*, 2007b; Latter *et al.*, 2007). The demographic data collected included: method of medication delivery, gender, age, nurse banding/ grade, highest educational qualification and clinical experience. The clinical scope of practice was also elicited, for sexual health this involved simple or advanced genitourinary medicine and/ or contraception. The second section involved responses to 11 positively worded attitude statements, which were based on themes presented throughout the 'Background' chapter. These statements were created specifically for the study and explored participants' opinions on how medication delivery: impacted on their clinical practice (Qu. 1, 2, 3); influenced patient experience (Qu. 4); affected their personal confidence and satisfaction in practice (Qu. 5, 6, 9); how training and continuing professional development prepared them (Qu. 7, 8); and whether they felt it was a worthwhile intervention (Qu. 10, 11). Participants were asked to circle a five-point 'Likert-type scale' detailing strong

disagreement (1) to strong agreement (5) to the statements. The last section of the questionnaire utilised governance and training legislation for medication delivery (NICE, 2014; DH, 2012; NMC, 2006), and the expertise of a health economist, nurse prescribing researcher and a senior sexual health nurse to determine the resources required for integrating, training and maintaining INP and PGDs in clinical practice. Participants were prompted to provide estimates/ recall of the resource implications to independently deliver medications. Separate INP (Appendix E) and PGD (Appendix F) questionnaires focussed on the components specific to each method. Participants also had the opportunity to leave 'comments' to expand their responses.

The benefit of using questionnaires in this way supported a standardised method of data collection across all participants, thus supporting quantitative analysis and the ability to create inferences. That being said, the questionnaires' structure limited the respondents' choices, and may have obliged participants to choose an option they may not have otherwise selected (Parahoo, 2006; Bowling, 2009; Moule & Goodman, 2009). Moreover, the questionnaires were not based on existing validated research tools; however, their content was based on existing evidence and were designed to collect specific data to answer the research question. The design was further enhanced as the aforementioned research team modified the content until full agreement was achieved. Once refined, the questionnaires were further peer reviewed by two separate senior sexual health nurses; who offered no further comments for refining or improvement. Following this process, questionnaires were deemed to have face and content validity, as they were focussed on measuring what they intended to measure; despite not being tested for validity or reliability (Parahoo, 2006; Bowling, 2009; Moule & Goodman, 2009).

5.4.3 Recruitment

All sexual health nurses at the participating sites (n=95) who used INP (n=28) or PGDs (n=67) were invited to complete a questionnaire following a presentation of the study during routine team meetings. An email detailing the study was also sent to the minority of nurses who could not attend the study presentation. The researcher attended staff meetings on all sites and offered to meet any potential participants one-to-one if they had any queries or would like to discuss participation.

The presentation of the study provided an overview of the entire project, but primarily focussed on what participation would involve (i.e. staff questionnaire, clinical diary, patient experience questionnaire and observational study). At the end of the presentation questionnaire packs were left with the local representative to distribute among eligible staff (i.e. INP and/ or PGD users working within sexual health). The pack contained: the questionnaire; participant information sheets for the questionnaire (Appendix D); the researchers' contact details for any queries; and a return envelope. At the end of the questionnaire there was an 'Expressions of interest' tear off sheet which invited staff to leave their contact details if they were interested in participating in the clinical diary. A participant information sheet for the clinical diary (Appendix I) was also included in the pack to facilitate an informed decision regarding further involvement. Once completed, participants were requested to seal their questionnaires in the envelopes provided and anonymously return them to the local representative. The researcher arranged personal bulk pick-up to avoid questionnaires being lost in the post.

5.4.4 Data collection

As the questionnaire contained three separate sections that required time to consider responses, the researcher requested questionnaires were returned within a two-week period. The time delay provided nurses time to consider participation in the questionnaire and subsequent study aspects. To support further submissions at the two-week period, either the researcher or the local site representative sent out email reminders to encourage further responses; this extended the submission period for a further two weeks. Completion and return of questionnaires were regarded as implied consent.

Upon receipt of the questionnaires, the 'expressions of interest' tear-off sheets were removed prior to reviewing any responses to enhance anonymity. These sheets were stored separately in a secure, locked drawer at the university and subsequently used for recruitment to the clinical diary. Data from the questionnaire were manually transferred to a specifically designed Microsoft Access® database by the researcher. All aspects of research governance and responsibility presented in Chapter 4 were adhered to.

5.4.5 Analysis

A power calculation was deemed unnecessary as the study capacity only allowed for five research sites. Therefore, a high response rate was sought to be able to infer and draw conclusions. Moule & Goodman (2009) suggest a response rate over 50% is generally deemed acceptable. Descriptive statistics were used predominantly in this section to describe nurses' age, clinical and professional experience and opinions on the impact medication delivery had on their practice. Where statistical test assumptions were met, the Chi-squared test and Independent Samples t Test were used to infer differences between INPs and PGD users, as described in 'Data analysis overview' on page 94. Findings from the staff questionnaires relating to costs are presented in Section 5.14 and 5.15.

5.5 Staff questionnaires: Findings

5.5.1 Response rate

Of 95 questionnaires distributed, 61 (64.2%) responses were received (INP=26, 92.8%; PGD=35, 52.2%). PGD users were less likely to respond than INPs (χ^2= 14.178, df= 1, p<0.001).

5.5.2 Demographic data

5.5.2.1 Gender, age & educational qualifications

Most staff participants were female (n=55, 90.2%) aged between 35 to 44 years (n=21, 34.4%). INPs were mostly aged between 35 and 54 years, Band 7 or above (n=18, 69%) and qualified to Masters Level (n=16, 61.5%). Whereas, PGD users were mostly Band 6 (n=24, 68.6%), but were more spread across all age categories and level of academic qualifications than INPs, see Table 5-5.

Table 5-5 Demographics of nurse questionnaire respondents

Demographics		INP (n=26)		PGD (n=35)		Total (n=61)	
		n	%	n	%	n	%
Gender	Female	21	80.8	34	97.1	55	90.2
	Male	5	19.2	1	2.9	6	9.8
Age range	25-34	3	11.5	8	22.9	11	18.0
	35-44	13	50.0	8	22.9	21	34.4
	45-54	9	34.6	10	28.6	19	31.1
	55-64	1	3.8	9	25.7	10	16.4
Band	5	0	0.0	5	14.3	5	8.2
	6	8	30.8	24	68.6	32	52.5
	7	13	50.0	6	17.1	19	31.1
	8 & 9	5	19.2	0	0.0	5	8.2
Qualification	Diploma	5	19.2	13	37.1	18	29.5
	Degree	4	15.4	8	22.9	12	19.7
	Masters	16	61.5	10	28.6	26	42.6
	PhD	1	3.8	0	0.0	1	1.6
	Unanswered	0	0.0	4	11.4	4	6.6

INP= independent nurse prescribing, PGD= patient group directions

5.5.2.2 Clinical experience

There was no difference between the groups with regards to the mean number of years participants had been qualified as a nurse (INP= 19.9 vs. PGD= 20.0: t= 0.035, df= 58, p= 0.972) or practising in sexual health (INP= 13.0 vs. PGD= 10.1: t= 1.954, df= 56, p= 0.056). PGDs had been used longer than INP by participants (7.6 vs. 5.2 years, respectively: t= -2.157, df= 56, p= 0.035: Table 5-6).

Table 5-6 Clinical experience of sexual health nurses by group

Clinical experience		INP (n=26)	PGD (n=35)	Total (n=61)
		n (%)	n (%)	n (%)
Years as a qualified nurse	No. of responses	26 (100)	35 (100)	61 (100)
	Range	6 to 35	3 to 45	3 to 45
	Mean	19.9	20.0	19.9
	Standard deviation	7.7	11.8	10.2
	Statistical testing	t =-0.035 (df58.2) p=0.972* mean difference= -0.1 (95% CI:-5.1 to 4.9)		
Years in clinical Practice	No. of responses	25 (96.2)	30 (85.7)	55 (90.2)
	Range	6 to 35	3.5 to 45	3.5 to 45
	Mean	18.8	19.6	19.0
	Standard deviation	7.5	11	9.5
Years in Sexual Health practice	No. of responses	26 (100)	32 (91.4)	58 (95.1)
	Range	4.5 to 23	2 to 23	2 to 23
	Mean	13.0	10.1	11.4
	Standard deviation	5.3	5.9	5.7
	Statistical testing	t = 1.954 (df56) p=0.056 mean difference= 2.9 (95% CI: -0.1 to 5.8)		
Years using nurse prescribing or PGDs	No. of responses	26 (100)	32 (91.4)	
	Range	0.5 to 11	0.2 to 16	
	Mean	5.2	7.6	
	Standard deviation	3.5	4.5	
	Statistical testing	t = -2.157 (df56) p=0.035 mean difference= -2.3 (95% CI: -4.5 to -0.2)		
INP previous use of PGD (yrs)	No. of responses	24 (92.3)		
	Range	0 to 15		
	Mean	5.9		
	Standard deviation	4.4		

*INP= independent nurse prescribing, PGD= patient group directions, t=Independent Samples t Test, No=number, CI= confidence interval. *Levene's Test equal variances not assumed.*

Twenty-two (84.6%) INPs reported they had used PGDs for a mean of 5.9 years prior to undertaking the prescribing course (see Table 5-6). A third of INPs at site 4 continued to use PGDs despite being qualified prescribers (see Table 5-7).

Table 5-7 Methods of medication delivery used by sexual health nurses by site

Medication delivery method		Site 1		Site 2		Site 3		Site 4		Site 5		Total	
		n	%	n	%	n	%	n	%	n	%	n	%
INP	INP responses	11	42.3	1	3.8	0	0.0	12	46.2	2	7.7	26	100
	INP only	11	100	1	100	0	0.0	8	66.7	2	100	22	84.6
	INP & PGD	0	0.0	0	0.0	0	0.0	4	33.3	0	0.0	4	15.4
PGD	PGD responses	6	17.1	4	11.4	4	11.4	10	28.6	11	31.4	35	100
	PGD only	6	100	4	100	4	100	10	100	10	90.9	34	97.1
	PGD & PSD	0	0.0	0	0.0	0	0.0	0	0.0	1	0.1	1	2.9

INP= independent nurse prescribing, PGD= patient group directions, PSD= patient specific directions (a medication treatment plan made specifically for individual/ specific patients)

INPs and PGD users practiced across genitourinary medicine and contraception; however, a higher percentage of PGD nurses overall (n=10, 16.4%), did not have any contraception training compared to genitourinary medicine (n=1, 1.6%). INPs were more like to be trained to advanced practice level in genitourinary medicine, compared to PGD users (80.8% versus 48.6%, respectively; χ2= 5.285, df=1, p= 0.022). There was, however, no difference with regards to whether or not INPs and PGD users practiced at advanced levels in contraception (46.2% vs. 45.7%, respectively; χ^2= 0.001, df=1, p= 0.973). See Table 5-8.

Table 5-8 Clinical competency of INPs and PGD users

Sexual health competency	INP (n=26)		PGD (n=35)		Advanced practice statistical testing* (INP vs. PGD)	Total (n=61)	
	n	%	n	%		n	%
Advanced genitourinary	21	80.8	17	48.6	χ^2= 5.285, df=1, p= 0.022	38	62.3
Simple symptomatic	3	11.5	17	48.6		20	32.8
Asymptomatic genitourinary	1	3.8	1	2.9		2	3.3
Working towards genitourinary competencies	1	3.8	0	0.0		1	1.6
Advanced contraception	12	46.2	16	45.7	χ^2= 0.001, df=1, p= 0.973	28	45.9
Basic contraception	12	46.2	11	31.4		23	37.7
No contraception	2	7.7	8	22.9		10	16.4

**Statistical testing compared 'advanced genitourinary' practice with combined totals of non-advanced genitourinary practice between INPs and PGD users; and similarly for advanced contraception. INP= independent nurse prescribing, PGD= patient group directions, vs.= versus, χ^2= Chi-squared test.*

5.5.3 Nurses' attitudes to independent delivery of medication

Both INP and PGD users provided positive responses to 11 attitude statements regarding the impact independent access to medication had on their practice. A detailed results breakdown is presented in Appendix AA. There were limited variations found between INPs and PGD users' opinions. Participants highlighted the following:

Clinical practice

Respondents in both groups predominantly agreed that independent access to medication made their clinical roles easier (INP=25, 96.3%; PGD=35, 100%); was essential for their roles (INP=23, 88.5%; PGD=33, 94.3%); and that their medication delivery skills were being used effectively (INP=24, 92.3%; PGD=29, 82.9%)

Patients' experience

Respondents were of the belief that patients received a better quality of care because nurses could independently deliver medications (INP=24, 92.3%; PGD=35, 100%).

Personal confidence and satisfaction

Both INP (n=25, 96.1%) and PGD users (n=30, 85.7%) identified that they felt confident in their ability to deliver medication independently, and that confidence in their clinical practice had increased since delivering medications independently (INP=22, 84.6%; PGD=30, 85.7%).

Training/ continuing professional development

There was slightly less confidence from nurse participants regarding the adequacy of training to prepare them for delivering medication independently; with 21 (80.8%) INPs and 26 (74.3%) PGD users agreeing it was sufficient. There was even less satisfaction from INPs relating to support for continuing professional development, with only 17 (65.4%) agreeing it was enough. This was less apparent in responses from PGD users (n=27, 77.2% agreeing).

Overall personal recommendations

Respondents reported that they would recommend independent medication delivery to departments not enabling nurses to do this (n=56, 91.8%), and that the effort to become

competent in the independent delivery of medications was worthwhile (n=54, 88.6%). While no-one disagreed with this final statement, four (11.4%) PGD users were neutral.

5.5.4 Motivation for independently delivering medications

INPs were predominantly motivated to prescribe to: enhance their clinical skills; improve patients' journey/ experience and personal job satisfaction; and to overcome medication restrictions (n=24, 92.3%). While these were also important motivations for PGD users, the main influencing factor for the majority of PGD users (n=30, 85.7%: see Table 5-9) was the expectation by their employer.

Table 5-9 Motivation in training to become INP or PGD users

Training motivation	INP (n=26)		PGD (n=35)		Total (n=61)	
	n	%	n	%	n	%
Enhance clinical skills	24	92.3	29	82.9	53	86.9
Improve patient experience/ journey	24	92.3	28	80.0	52	85.2
Expectation from role/ employer	16	61.5	30	85.7	46	75.4
Increase knowledge of medicines/ pharmacology	20	76.9	22	62.9	42	68.9
Facilitate service development	20	76.9	26	74.3	46	75.4
Improve satisfaction in your role	24	92.3	29	82.9	53	86.9
Remove existing restrictions to medication delivery	21	80.8	24	68.6	45	73.8
Obtain academic credits	10	38.5				

INP= independent nurse prescribing, PGD= patient group directions

5.5.5 PGDs likelihood to undertake INP training

Over 40% (n=13, 40.6%) of PGD users reported they would be very likely/ likely to undertake INP training. Similar numbers (n=13, 40.6%) reported they would be unlikely/ very unlikely to do so. See Table 5-10. The remaining 18.8% (n=6) could be encouraged to undertake INP training.

Table 5-10 Likelihood of PGD users undertaking INP training

Likelihood of INP training	Number of responses (n=32)	
	n	%
Very unlikely	6	18.8
Unlikely	7	21.9
Neutral	6	18.8
Likely	5	15.6
Very likely	8	25.0

INP= independent nurse prescribing, PGD= patient group directions

Content analysis of PGD users' free-text comments relating to INP training identified that of those PGD users keen to undertake the INP training course, three had experienced resistance from their managers, despite detailing potential clinical benefits. By contrast, in a site that fully supported INP, it was highlighted that a Band 6 was unable to become an INP because of local restrictions that determined INPs needed to be Band 7 (n=1). PGD users (n=5) reported that as they became more senior and began managing more clinically complex presentations, they started noticing inherent restrictions associated with PGDs, and saw the benefits of INP. Two respondents reported that they were happy to continue to use PGDs, as they were suitably "wide-ranging and sufficient to cover their sexual health role."

5.6 Clinical diary: Task-specific methods

5.6.1 Purpose

Diaries were used by nurses to keep a record of their clinical activities over a two-week period. Although diaries are more commonly used in qualitative research, they are useful for collecting structured quantitative data as a complementary research design (Bowling, 2009; Moule & Goodman, 2009). Within the context of this study, the diary supported the collection of standardised data on nurses' consultations activity across all five sites.

5.6.2 Method design

The clinical diary (Appendix G) was specifically designed for the study, initially based on the researcher's expert knowledge of sexual health and patients' journeys through the service. The diary was further refined in conjunction with the study supervisors, who provided theoretical and practical research expertise to ensure only relevant data were collected. The circling of coded responses aimed to make diary completion quick, simple and efficient; however, it did rely on participant's commitment to ensure reliable and accurate completion. The primary purpose was to determine the frequency of medication provision and consultation length to support cost and resource assessments. The aim of nurses delivering medication independently was to facilitate autonomy (NMC, 2006); however, clinical and/ or medication support is frequently sought through the multi-disciplinary team (Black, 2013). The diary recorded: patients' clinic IDs and type of consultation (new or follow-up); frequency and independence of medication provision; whether any clinical and/ or medicinal advice was sought from a colleague; and an approximation of time required to manage individual care episodes. Explanatory notes (Appendix H) formed the front page of the diary to provide detailed guidance and act as a reference point for accurate completion.

To improve the dairy's validity and reliability it was piloted (Moule and Goodman, 2009) by four experienced sexual health nurse practitioners. During piloting, aspects associated with: recording durations of consultations; categorisation of type of advice sought (clinical management and/ or

medicinal); and instructions on how to complete the diary were raised. Those piloting it found it was difficult to provide precise consultation durations. Incorporating scales (e.g. 0-5; 6-10) made the chart overly encumbered. Following feedback and liaising between those piloting the diary and the study supervisors, three columns were agreed on for participants to handwrite an estimated consultation duration, specifically: 'Patient-facing time'; 'Non-patient facing' and 'Time with other professional'. A suggestion to differentiate between 'clinical management' and 'medicine' advice was also added because of user feedback, thus producing practical information on the nature of advice sought. The diary's explanatory notes (Appendix H) were also modified to be clearer in terms of phrasing and formatting. The definitive version of the diary incorporated all the suggested feedback, and was subsequently used in the study.

The diary was also used to distribute the patient experience questionnaires (Appendix L) to patients who received medication from nurse participants (see section 5.12).

5.6.3 Recruitment

Respondents who submitted an expression of interest form from the staff questionnaire were contacted by the researcher to discuss participation in the clinical diary, initially by email then in person. A participant information sheet (Appendix I) and consent form (Appendix J) were emailed to each potential participant at least 48 hours prior to the researcher arriving on site. A discussion on the diary was undertaken on a one-to-one basis, with an opportunity to ask questions. Prior to asking the participants to sign the consent forms, the voluntary nature of participation was emphasised, as was the ability to withdraw at any point.

5.6.4 Data collection

Completion of diaries had the potential to alter behaviour as participants were aware they were being monitored. They could also lead to participant burden and fatigue (Moule and Goodman, 2009). To achieve enough diary entries, but avoid overly burdening participants, a period of two weeks was decided and agreed by the study supervisors. This was defined as two normal working weeks for that individual; taking into consideration long days and part time hours, rather than

simply specifying 10 working days. If participants were sick or on annual leave during the data collection period they were asked to include additional days to represent two normal working weeks of data. Participants were free to select their own suitable two-week period.

During data collection, some further issues became apparent that were not raised during piloting. There was initial confusion relating to which patients needed the questionnaire. This was clarified as per the instruction sheet on the front page. Once this aspect became apparent, the distribution of patient questionnaires was emphasised to all subsequent nurse participants to ensure accurate understanding. Initially some other nurses were only recording patients they gave medication to, the need to include all patient contact was also clarified with all participants. Some PGD users became confused with the words “independently completed” in the ‘Medication delivery’ column; assuming this referred to INPs, as opposed to independent medication delivery. Clarification was provided. The term ‘autonomous practice’ was subsequently used throughout the study to ensure this differentiation was clear.

The diary recorded patient clinic numbers and dates of birth, however, did not include patient names or diagnoses. Patient confidentiality was of upmost importance and a consideration throughout the diary design and data collection processes. Upon completion, participants were requested to seal their diaries in the envelopes provided and anonymously return them to the site representative. The researcher arranged to collect them in bulk to avoid them getting lost in the post. Once received, the data from the diaries were transferred onto a specifically designed Microsoft Access® database. All aspects of research governance and responsibility presented in Chapter 4 were adhered to.

5.6.5 Analysis

Much of the data collected in the diaries was categorical, therefore the Chi-squared test was used to determine potential differences between INP and PGD users’ consultations in terms of: presentation type (new versus follow-up); medication delivery frequency; need to obtain support from professional colleagues. Patients’ age (where possible), consultation length and length of time other professionals spent supporting participants was presented in terms of mean, standard deviation, range. The Independent Samples t Test was the used to infer if any differences existed

between INPs and PGD users. PGD users were particularly underrepresented in the diary in relation to the overall percentage employed at each site. The relatively high number of actual diary entries from both groups should, however, reduce any potential differences being down to chance. The effects of 'new' versus 'follow-up' care episodes, medication delivery and study type (INPs or PGD users) on consultation length were tested statistically using a general linear model (GLM). To test whether study type moderated the effects of 'new' versus 'follow-up' and medication delivery on consultation length interaction (moderating) terms were added to the main effects model that already included 'new' versus 'follow-up', medication delivery and study type. If the moderating effects were not statistically significant the GLM without moderating effects was used to test the main effects (i.e. the effect of each independent variable adjusting for the two other variables in the model). F-tests (with degrees of freedom and p-values) for moderating effects and main effects have been presented in the results.

5.7 Clinical diary: Findings

5.7.1 Response rate

Expressions of interest for participation in the clinical diary were received from 17 (65.8%) INPs and 22 (62.9%) PGD users from the questionnaire. This represented 60.7% of INP and 32.8% of PGD nurses across the five sites. All respondents who expressed interest in the clinical diary consented to participate; 17 (100%) INPs and 19 (86.4%) PGD users subsequently returned their completed documents. Three PGD users withdrew.

5.7.2 Nurses' clinical diary activity

The 36 submitted diaries provided 1,330 clinical entries (INP=737; PGD=593). See Table 5-11 for a summary and Appendix BB for detailed breakdown. INPs were more likely to manage new episodes of care compared to PGD users (69.5% vs. 49.6%, respectively: χ^2= 47.75, df= 1, p<0.001: Table 5-11). There was no difference in the frequency of medication provision between INPs and PGD users (62.4% vs. 58.7%: χ^2 = 1.97, df = 1, p=0.168); however, INPs were more likely to deliver medication autonomously (91.1% vs. 70.4%: χ^2 = 57.88, df = 1 p<0.001) and less likely to seek advice from professional colleagues (10.2% vs. 13.8%: χ^2 = 3.97, df = 1, p=0.046) compared to PGD users. See Table 5-11. INPs (n=38, 50.7%) were more likely to seek clinical management advice compared to PGD users who equally sought medication (n=21, 25.6%) and clinical advice (n=20, 24.4%: χ^2 = 37.922, df= 2, p=0.019). Both groups predominantly consulted doctors when seeking advice. Thirty (8.6%) PGD users' episodes required professional colleagues to write prescriptions.

Patients managed by nurse participants during the diary were aged between 13 to 78 years, with a mean age of 28.6 years. There was no difference in patients' ages between INPs and PGD users (t =0.826, df= 1170.5, p=0.409: Table 5-12).

Table 5-11 Summary of diary results

Diary entries (n=1330)		Total				Statistical testing (INP vs. PGDs)*
		INP (n=737)		PGD (n=593)		
		n	%	n	%	
Presentation	New	512	69.5	294	49.6	χ^2 =47.747, df =1, p<0.001
	Follow-up	220	29.9	280	47.2	
	Both	0	0.0	1	0.2	
	Missing	5	0.7	18	3.0	
Medications given?	Med given	460	62.4	348	58.7	χ^2 =1.972, df =1, p=0.168
	No meds	261	35.4	232	39.1	
	Missing	16	2.2	13	2.2	
Advice sought	Advice sought	75	10.2	82	13.8	χ^2 =3.966, df =1, p=0.046
	No advice Sought	580	78.7	451	76.1	
	Missing	82	11.1	60	10.1	
Type of advice	Clinical	38	50.7	20	24.4	χ^2 =7.922, df =2, p=0.019
	Medicine	12	16.0	21	25.6	
	Both	13	17.3	12	14.6	
	Missing	12	16.0	29	35.4	
Advice obtained from	Doctor	42	56.0	60	73.2	Doctor vs. others combined χ^2 =0.532, df =1, p=0.466
	Nurse	3	4.0	6	7.3	
	Pharmacist	5	6.7	1	1.2	
	Health Adviser	2	2.7	3	3.7	
	Missing	23	30.7	12	14.6	
Medications given		**460**	**62.4**	**348**	**58.7**	
Medication delivered?	Autonomously	419	91.1	245	70.4	χ^2=57.878, df=1, p<0.001*
	Rx: Doctor	29	6.3	80	23.0	
	Rx: Nurse	2	0.4	10	2.9	
	Rx: Pharmacist	3	0.7	3	0.9	
	Rx: Health Adviser	2	0.4	1	0.3	
	Rx: Missing	5	1.1	9	2.6	
	No PGD			30	8.6	

**Statistical testing does not include data from the grey sections (e.g. 'Both' or 'Missing')*
***combines prescriptions from all professions and compares against nurses' autonomous practice*
INP= independent nurse prescribing, PGD= patient group directions, vs.= versus, $\chi^{2=}$ Chi-squared test, Meds= medications, Rx= prescription, No PGD= no valid PGD for care episode

Table 5-12 Patients' age demographics

Data type	INP	PGD	Total	Statistical testing (INP vs. PGD)
Mean (years)	28.8	28.3	28.6	t =0.826, df= 1170.5, p=0.409 mean difference 0.6 (95% CI: -0.6 to 1.5)*
Standard deviation	9.5	10.8	10.1	
Range	13 to 78	13 to 74	13 to 78	

*INP = independent nurse prescribing; PGD = patient group directions; t=Independent Samples t Test; CI= confidence interval. *Levene's Test equal variances not assumed.*

5.7.3 Consultation length

Overall, INPs statistically spent longer managing patient presentations compared to PGD users (mean of 24.9 vs. 22.8 minutes, respectively: t=2.597, df=1,144, p=0.010: Table 5-13). However, when consultations were compared like-for-like there were no statistical differences found between INPs and PGD users' new (mean 27.3 vs. 25.7 minutes respectively: t=1.434, df=694, p=0.152) or follow-up consultation lengths (mean 19.6 vs. 20.0 minutes, respectively: t=-0.338, df=448, p=0.736). These times also do not account for complexity of patients' presentations.

Table 5-13 Overall time spent managing patient care episodes

Type of attendance	Measurement	Total nurses' time managing patients		Statistical testing
		INP	PGD	
Overall	Number of entries (% of expected values*)	589/737 (79.9%)	557/593 (93.9%)	t= 2.597, df= 1144, p= 0.010
	Range (mins)	1** to 84	5 to 95	
	Mean (mins)	24.9	22.8	
	Standard deviation	12.9	13.9	
New	Number of entries	412	284	t=1.434, df=694, p=0.152
	Range (mins)	1** to 84	5 to 95	
	Mean (mins)	27.3	25.7	
	Standard deviation	13.0	15.1	
Follow-up	Number of entries	177	273	t= -0.338, df=448, p0.736
	Range (mins)	5 to 60	7 to 75	
	Mean (mins)	19.6	20.0	
	Standard deviation	10.8	12.0	

**number of episodes included in the diary where a face-to-face time was expected*
***INP prescribed for another nurse, but did not physically manage the patient so entered '1' minute*
INP=independent nurse prescribing, PGD= patient group directions, mins= minutes, t= Independent Samples t Test

The effects of 'new' versus 'follow-up' care episodes (mean difference=6.8 minutes) and whether medication delivery (mean difference=1.9 minutes) impacted on consultation length is presented in Table 5-14. Neither new episodes of care (F[1,1141] = 1.31, p=0.25) nor provision of medication (F[1,1141] = 0.36, p=0.55) were moderated by study type. Unsurprisingly, new episodes of care (F[1,1143= 68.76, p<0.001) and the provision of medication (F[1,1143] = 4.13, p=0.042) increased consultation length. These outcomes were consistent regardless of whether the patient was managed by an INP or PGD (F[,1,1143] = 0.59, p=0.44).

Table 5-14 Face-to-face time (minutes)

Face to face time*	INP (n=591)				PGD (n=563)				Total (n=1,154)			
Missing entries	146 (19.8%)				30 (5.1%)				176 (13.2%)			
Face-to face time (mins)	Total	Range **	Mean	St. Dev.	Total	Range	Mean	St. Dev.	Total	Range	Mean	St. Dev.
Overall	14,701	1 to 84	24.9	12.9	12,859	5 to 95	22.8	13.9	27,560	1 to 95	23.9	13.4
New episode	11,234	5 to 65	27.2	13.0	7,309	5 to 95	25.7	15.1	18,543	5 to 95	26.6	13.9
Follow-up episode	3,467	1 to 60	19.5	10.9	5,465	5 to 75	19.4	12.0	8,932	1 to 75	19.8	11.5
Medication given	10,193	1 to 65	25.7	12.7	7,876	5 to 95	23.3	14.2	18,069	1 to 95	24.6	13.5
No medication given	4,493	5 to 84	23.3	13.1	4,983	5 to 90	22.1	13.3	9,476	5 to 90	22.7	13.2
New WITH medication	7,965	1 to 65	28.1	12.8	4,498	5 to 95	26.5	15.6	12,463	1 to 95	27.5	13.9
New WITHOUT medication	3,269	5 to 84	25.1	13.2	2,811	10 to 90	24.7	14.2	6,080	5 to 90	24.9	13.7
Follow-up WITH medication	1,224	5 to 60	19.4	12.2	2,162	5 to 60	19.7	11.8	3,386	5 to 60	19.6	11.9
Follow-up WITHOUT medication	2,228	1 to 60	19.5	10.2	3,303	5 to 75	20.1	12.1	5,531	1 to 75	19.9	11.3

**This table presents the same data presented in four separate ways:*
Overall : combines the total face-to-face times nurses spent with patients
New or Follow-up: determines if differences in face-to-face times are related to whether a patient presented as a new episode of care or a follow-up
Medication given or not given: determines if differences in face-to-face time are related to whether medication is given or not
New/ follow up, with/without medication: determines if differences are related to a combination of both type of episode presentation and whether medication was delivered or not.
***one INP participant put a value of '1' minute in their diary when providing 'adhoc' prescriptions to patients they were not directly managing, identifying they supported another member of the team.*
INP=independent nurse prescribing, PGD = patient group directions, mins= minutes, St. Dev. = standard deviation

5.7.4 Support from professional colleagues

Although INPs required less support from professional colleagues than PGD users (10.2% vs. 13.8% of consultations, respectively: χ^2 = 3.97, df = 1, p=0.046), when INPs sought help, their colleagues spent longer supporting them compared to PGD users (11 minutes versus 8.2 minutes respectively); however, this was not statistically significant (t = 1.707, df = 92.7, p=0.091: see Table 5-15).

Table 5-15 Colleagues' time for advice or prescriptions (minutes)

Measurement	Total colleagues face to face time (minutes)		
	INP (n=95*)	PGD (n=152*)	Total (n=247*)
Number of entries (% of expected values)	63 (66.3%)	87 (57.2%)	150 (60.7%)
Range (minutes)	1 to 47	2 to 45	1 to 47
Mean (minutes)	11.0	8.2	9.4
Standard deviation	11.7	6.9	9.3
Statistical testing	t = 1.707, df=92.7, p=0.091** mean difference 2.8 (95% CI: -0.5 to 6.1)		

**number of episodes where either advice or medication was obtained from a professional colleague*
***Levene's Test equal variances not assumed*
INP= Independent nurse prescribing, PGD= patient group directions, t= Independent Samples t Test, CI= confidence interval

5.8 Clinical notes review: Task-specific methods

5.8.1 Purpose

The clinical notes review enabled a quantitative exploration of the safety and appropriateness of medication delivery by sexual health nurses. This also enabled an evaluation of nurses' scope of practice in terms of the conditions they managed and the range of medications they required access to. Patients' diagnosis, existing medical history, medication provision and documentation within clinical records were used to assess overall safety and appropriateness of care for individual episodes. In addition, episodes of care where patients did not receive medication were evaluated to ensure it was appropriate not to provide it (e.g. it would be appropriate to offer emergency contraception after recent pregnancy risk). Undertaking a thorough investigation in this way was intended to increase the generalisability of the findings and the inferences regarding safety and appropriateness of medication delivery by UK sexual health nurses. Moreover, it may well have implications for other clinical fields where non-medical practitioners independently assess, diagnose, treat and discharge patients attending for episodic healthcare.

5.8.2 Method design

The initial governance approval (REC, 28/05/2015) intended to use the clinical diaries to locate the clinical notes. However, during the data collection in the preceding phases several factors became apparent which weakened the robustness of this design. These involved: fewer number of PGD participants than predicted; reduced number of diary entries as nurses had multiple non-patient facing roles and part time hours; and each site undertook the diary's data collection at different time points. This consequently meant the results may have been biased towards INP, non-comparable between sites, and under-powered as minimum sample sizes may not have been achieved. A substantial amendment was therefore agreed (REC, 21/02/2016), which sourced the patients' notes from clinic attendance lists rather than the clinical diary. All sites provided lists of patient attendances between 01/07/2015-31/12/2015 (limited to all to INP and PGD users were possible), thus standardising the timeframe across all sites. This also had the

benefit of including all INP and/ or PGD users, as an audit design was employed rather than relying on staff volunteering. Consequently, this design is more likely to represent actual practice and it provided enough data to achieve the minimum sample size targets (presented later in this section).

Reviewing clinical documentation was incorporated as it provided key data components to assess safety and appropriateness of care as documentation was expected to provide accurate synopses of care provision (NMC, 2015). The use of existing documentation had the benefit of: not requiring additional staff participation; reduced researcher bias as conclusions were drawn from what was or was not documented; and the data were readily available (Moule and Goodman, 2009). Relying on data not specifically collected for research purposes may, however, impact on the specificity as this was not the primary function of the original documentation. Furthermore, clinical records only represented what was documented, rather than actual practice (Moule and Goodman, 2009). Nevertheless, the clinical notes were a valuable source of data to explore medication delivery.

A sample size calculation for the minimum number of clinical notes to include identified 344 clinical episodes per group. This calculation, made in conjunction with a statistician, assumed 99% of care episodes from INP were appropriate, compared with 89% of PGD; based on Black's (2013) study. An estimated six-month population size of 6,475 care episodes was based on a nurse practitioner managing three patients per hour, one four-hour clinical shift per day, five days a week, for two weeks by ten nurse participants per site. However, this figure, in retrospect, over-estimated the population as many sexual health nurses have multiple roles that are not always patient facing, and it did not consider part time workers. Nevertheless, the power calculation identified: "ignoring the structure of the data, where patients are nested within nurses, and some nurses are probably better than others at prescribing. With 344 patients per group, we have 99% power at the 5% significance level to find a difference between rates of appropriate prescribing of 90% compared to 98%, at the 5% significant level." (Personal communication with statistician, 2013).

Four distinct groups were determined to achieve a robust quantitative assessment of safety and appropriateness of nurses' medication delivery. A minimum of 344 clinical episodes in each group was the minimum target, based on the power calculation, as presented in Box 5.1.

Box 5.1 Minimum sample size of notes for each research group

1. Medication episodes primarily managed by INP (n=344: “INP med”)
2. Medication NOT provided in episodes managed by INP (n=344: “INP no med”)
3. Medication episodes primarily managed by PGD (n=344: “PGD med”)
4. Medication NOT provided in episodes managed by PGD (n=344: “PGD no med”)

Assessments of non-provision of medication was an essential component of study, as not providing medication to patients in certain circumstances may have been unsafe and/ or inappropriate. Examples include: incorrect management of sexual infections or partner notification causing STI to remain infective; not offering vaccinations, thus leaving high risk patients susceptible to preventable infections; inappropriate advice/ provision of contraception or emergency contraception puts females at risk of unwanted pregnancies; and not appropriately offering post exposure prophylaxis, following high-risk sex, could lead to HIV acquisition (BASHH, 2016; FSRH, 2016).

The type of data collected ensured assessments could be made based on the patients’ demographic risk factors, existing medical conditions, concurrent medication, pregnancy risk and diagnosis. Assessments then reviewed drug choice, prescription documentation, drug appropriateness, unexpected re-attendance for the same issue and independence of practice. Data collected were based on: prescribing frameworks (RPS, 2016), local policies, relevant BASHH (2016) and FSRH (2016) guidelines, the BNF (2016), and legislation influencing how nurses deliver medications independently (DH, 2006; NMC, 2006; The Human Medicines Regulations 2012; NICE, 2014).

Assessing clinical practice in this way adopted an implicit review, resulting in a single person’s interpretation of clinical practice, thus opening the study to bias. To reduce interpretation bias and improve validity and reliability, additional precautions were integrated within the study design. The researcher discussed every episode of substandard practice, plus any issues where uncertainty existed, with a local representative. Local representatives were all experienced senior sexual health nurse prescribers (except site 3, who was the PGD author). Consensus was achieved in all queries between the researcher and the local representative prior to final reporting. A further 10% of each site’s clinical notes quota (see Recruitment 5.8.3) were also randomly checked by

the local representative. Randomisation occurred using the 'Study IDs' from each site, including only episodes where medication was delivered. The relevant list was exported into an Excel® spreadsheet, was allocated a random number, and then sorted lowest to highest. Clinical notes were then checked in ascending numerical order by the local representative until the original 10% quota was achieved. An experienced in HIV/ sexual health pharmacist independently assessed the medication safety of a 10% random sample (same randomisation process) of clinical notes where patients had a documented medical condition, concurrent medication and/ or allergy. The pharmacist also provided advice on four complex medication cases.

5.8.2.1 Measuring appropriateness of medication delivery with a validated research tool

The Medication Appropriateness Index (MAI: Hanlon *et al.*, 1992) was used in this study to measure appropriateness of prescribing (in conjunction with local and national guidelines, and prescribing error definitions). Multiple other tools existed to assess prescribing practice; however, given the vast variations in patient presentations, no single tool accurately assessed all types of medication provision (Kaufmann *et al.*, 2014). Choosing the assessment resources to use in this study was an important methodological consideration to ensure accurate, meaningful evaluations that were based on valid and reliable tools (Latter *et al.,* 2007). The 'structured systematic overview of published assessment tools' (Kaufmann *et al.*, 2014) reviewed 46 different prescribing assessment tools. However, most of these targeted specific patient populations; most commonly elderly (n=36, 78%), in-patient (n=4, 8.5%) or ambulatory (n=9, 19.5%) care. Tools that specifically assessed older adults, drug-drug interactions or were disease specific (i.e. renal disease, liver disease, diabetes mellitus or other long-term conditions) were excluded as sexual health attendees are predominantly younger, less likely to have multiple comorbidities or polypharmacy and therefore required more generic assessments. This resulted in a choice between the 'Medication Appropriateness Index' (MAI: Hanlon *et al.*, 1992), the 'Robertson's Flow Charts to prevent, identify and resolve Drug therapy Problems' (Robertson, 1996) and the 'Kaiser Permanente Model' (Raebel *et al.*, 2007). Based on the extensiveness and range of measurement factors (Kaufmann *et al.*, 2014), the MAI appeared to be the most comprehensive tool. Furthermore, Latter *et* al. (2007) determined that the MAI was 'relevant and meaningful in evaluating the clinical appropriateness of nurses' prescribing decisions' (p418), and it demonstrated good inter/ intra-rater reliability, content validity and had successfully assessed medical and pharmacy consultations (Latter *et al.*, 2007). The MAI questions 10 specific areas

(see Box 5.2) related to medication choice; typically, with four responses: 'indicated', 'intermediate', 'not indicated' or 'not sufficient information' (Hanlon et al., 1992).

Box 5.2: Medication Appropriateness Index (MAI: Hanlon *et al.*, 1992)

1. Is there an indication for the drug?
2. Is the medication effective for the condition?
3. Is the dosage correct?
4. Are the directions correct?
5. Are the directions practical?
6. Are there clinically significant drug-drug interactions?
7. Are there clinically significant drug-disease/ condition interactions?
8. Is there unnecessary duplication with other drug(s)?
9. Is the duration of therapy acceptable?
10. Is this drug the least expensive alternative compared with others of equal utility?

Latter et al., (2007b), Latter et al., (2012) and Naughton et al., (2012) have successfully used the MAI to assess nurse prescribing. Utilisation of the tool was not found to be time intensive. Naughton *et al.* (2012) found considerable differences between reviewers (Cohen's kappa statistic for inter-rater reliability was 0.19, which is very poor: Naughton *et al.*, 2012); but only used two 'prescribing experts' to assess a wide range of clinical specialities where a more specialist in-depth clinical knowledge may have been required to make accurate assessments. Conversely, Latter *et al.* (2012) used 20 "experienced prescribers" to each assess 20 transcripts, and found little variation between the overall scores; an Analysis of Variance identified high level of positive agreement between raters (84.5%, n=3,381), which increased (93.7%, n=3748) when ambiguous 'not known', 'not applicable' or 'missing' data were removed. The MAI has been shown to support exploration of the appropriateness of medication provision in nurse prescribing research (Latter *et al.*, 2007; Latter *et al.*, 2012).

Consequently, the MAI was used in this study to assess the appropriateness of medication choices in the clinical notes review and the consultation observations. Components deemed

'inappropriate' during assessments with the MAI were allocated a prescribing error category, as guided by Dornan *et al.* (2009); and allocated a severity rating (Dean and Barber, 1998; Avery et al., 2012). It should, however, be noted that the MAI is not effective with regards to the determination of appropriateness of 'omitted drugs' where medication is indicated for a patient, but not provided (Marie-West *et al.*, 2012). The researcher used national and local guidelines and their own clinical expertise to determine if medication was inappropriately not provided. The researcher was an experienced senior sexual health advanced practice nurse, therefore had the expertise to make clinical judgements using the MAI and non-provision of medication. To enhance reliability and validity of the findings, a random selection of 10% of each sites' sample size quota were independently re-assessed, as was all queries and omissions/ error categories, as previously described.

Some patients received more than one drug, therefore analysis of prescription completeness and assessments using the Medication Appropriateness Index (MAI) undertook assessments for each individual drug. The MAI used mean, standard deviation, range and the Independent Samples t Test to demonstrate similarities between INP and PGD. MAI scores range from 0 (all appropriate) to 18 (all inappropriate). The closer to '0', the more appropriate medication delivery is. The weighting to each MAI questions were grouped as detailed in Table 5-16.

Table 5-16 Medication appropriateness index weighted questions scoring

Group	Questions	Appropriate & intermediate scores	Inappropriate & unknown scores
A	Indication; effectiveness	0	3
B	Dosage; correct directions; drug-drug interactions; drug-disease interactions	0	2
C	Practical directions; costs; duplication; duration	0	1

(Hanlon, *et al.,* 1992)

5.8.3 Recruitment

The clinic notes review adopted an audit design; therefore, individual staff or patient consent was not required, as authorised by Caldecott Guardian, REC and R&D approvals. Each site provided a list of patient attendances between 01/07/2015 and 31/12/2015, filtered to include eligible nurses where possible. If the clinic lists contained patients' names or addresses these were immediately deleted, and not used in working documents. As the clinical notes data collection

was during a similar timescale to commencement of the entire study, the clinical notes review reflected the practice of nurses from the preceding tasks. The six month timescale standardised the recruitment of clinical records across all five sites.

The minimum quota of clinical records required from each site was stratified to be proportionate to the percentage of INPs/ PGD users at each corresponding department. As demonstrated in Table 5-17, site 1 had 39.3% of the total INPs, therefore site 1 were allocated 39.3% of the 344 quota for INPs (135.1 notes per INP group, rounded up to 136). Each site's distinct clinic attendance lists were stored on a separate Microsoft Excel® spreadsheet, and each entry was allocated a random number by Microsoft Excel®. Each distinct list was then sorted into ascending numerical order, and the corresponding clinical notes were reviewed in that order. Recruitment continued to each of the four groups until the last group achieved the minimum quota (meaning three groups exceeded their minimum quota). The inclusion/ exclusion criteria are presented in Table 4-4 on page 92 in 'Chapter 4: Methods'.

Table 5-17 Stratified sample size quotas per site

Site	INP			PGD		
	No. at site	% at site	Notes /group	No. at site	% at site	Notes /group
1	11	39.3	**135.1**	14	22.2	**76.4**
2	1	3.6	**12.3**	8	12.7	**43.7**
3	0	0.0	**0.0**	10	15.9	**54.6**
4	13	46.4	**159.7**	16	25.4	**87.4**
5	3	10.7	**36.9**	15	23.8	**81.9**
Total	**28**	**100.0**	**344.0**	**63**	**100.0**	**344.0**

INP= independent nurse prescribing, PGD=patient group directions

5.8.4 Data collection

The researcher attended each site to collect data at mutually convenient times. Data from the clinical notes were recorded on a specifically designed Microsoft Access® database (Appendix K), which was adapted from a similar project undertaken by the researcher (Black, 2013). The original version was adapted to incorporate: the validated MAI tool; a review of the appropriateness of non-provision of medication; and unexpected re-attendance related to the

initial complaint. Data were recorded that were determined, by the researcher and their supervisors, to be relevant to make judgements on the safety and appropriateness of medication delivery, as presented in the 'Method design'. The data collection tool was subsequently considered to have content and face validity; however, only the MAI had proven reliability and validity (Hanlon *et al.*, 1992). No structural changes were made to the tool during data collection. Appendix K presents the field list and purpose of that data.

During data collection, no patient identifiable information were stored on the data collection tool, instead separate Microsoft Excel® sheets were used to record the automated 'ID' number generated by Microsoft Access® during data entry. Consequently, individual clinic numbers could be traced back without having them stored on the data collection tool. Relevant demographics regarding patients' ethnicity, gender, sexuality and age were recorded as these had implications for the patients' clinical management.

There was an ethical clause that in the unlikely situation of discovering criminal activity, the researcher was to report this to an appropriate local manager, but this was not required. All aspects of research governance and responsibility presented in Chapter 4 were adhered to.

5.8.5 Analysis

Due to the various perspectives explored in this method, the sample sizes differ throughout based on the aspect under review (e.g. whether or not medication was delivered; specifically looking at medication consultations; or reviewing individual drugs delivered). The data analysis structure and associated sample sizes are summarised in Figure 5-1 on page 153. Analysis was split into: 'Medication delivery frequency', 'Clinical characteristics & activity', 'Review of medication consultations & Individual drug assessments', 'Synthesis of clinical errors, appropriateness & safety'.

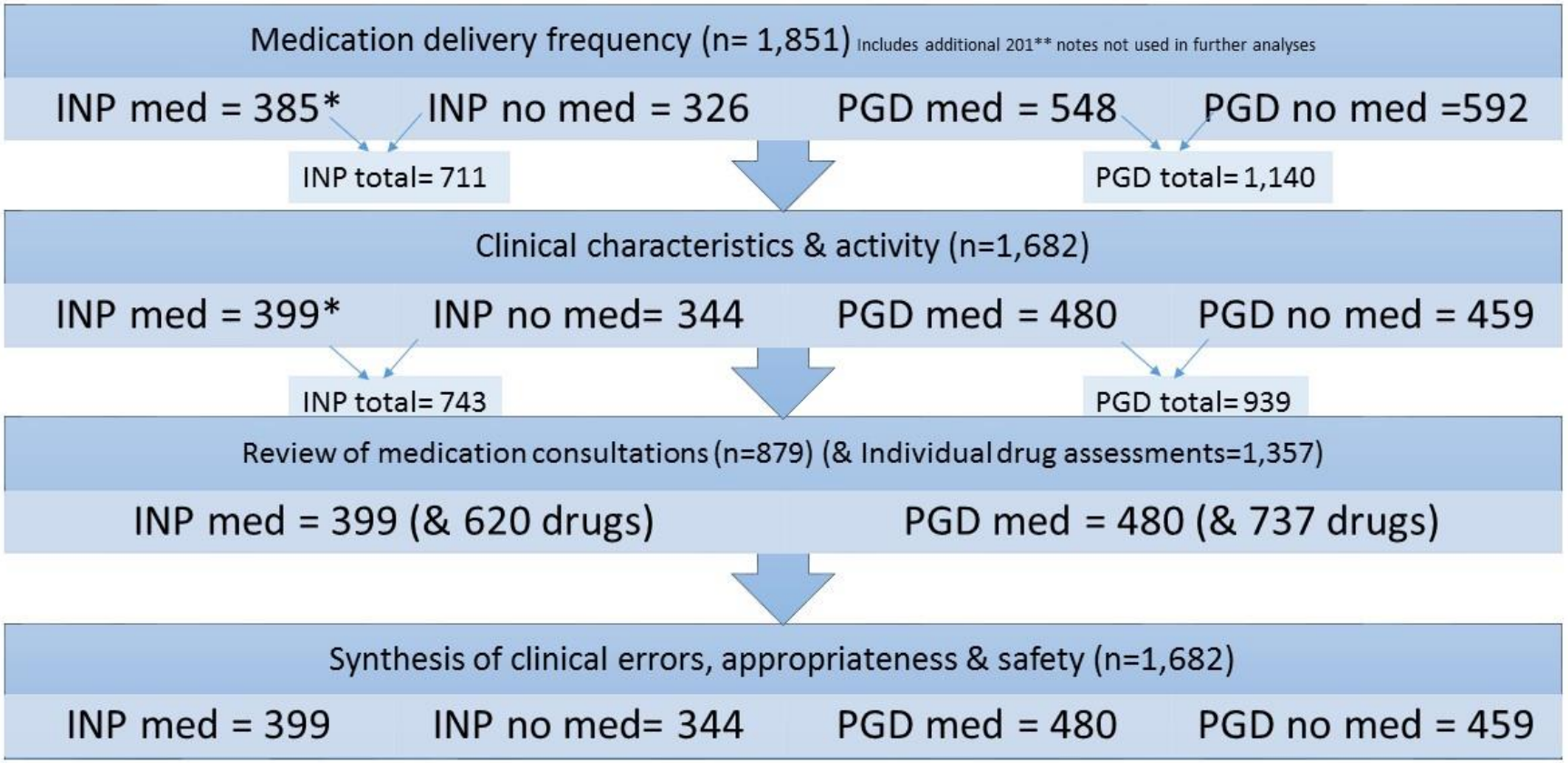
The sample size calculation identified that a minimum of 344 care episodes in each of the four research groups was required for statistical testing (see Table 5-17 on page 149). The PGD groups achieved their quota far quicker than INPs, but to accurately assess frequency of medication delivery, data collection continued until the smallest group neared completion.

Frequency analysis included 1,851 care episodes, whereas detailed consultation reviews only included 1,682 as detailed data collection on PGD users' care episodes stopped to ensure a more equal spread of analyses between groups. Thirty-two INP clinical notes were not included in frequency analysis; as medication delivery frequency could not be calculated from site 2 (as clinic lists for patients who were delivered medication could not be obtained, n=14). Moreover, 18 records where INPs did not deliver medication were sourced from the clinical diary rather than attendance lists (as it was not possible to source these last 18 from attendance lists at sites 2 and 5 within the study's timeframe).

Data from the clinical notes reported on patients' gender, age, ethnic origin, sexuality, presentation type, diagnoses, whether medication was delivered and if nurses completed care episodes autonomously. Descriptive data on the support resources from professional colleagues were also recorded. Consultations where medications were delivered explored the types of medication, potential risk factors (e.g. interactions with existing medical problems), appropriateness and safety. MAI assessments for each drug were undertaken as distinct measurements to allow clearer comparisons between INPs and PGD users. Clinical governance properties unique to PGDs were presented separately. Assessments of patient presentations were also made to determine if medication was not provided or offered, despite it being indicated (i.e. to ensure it was appropriate not to provide medication). Mean, standard deviation and range were presented for continuous measures and frequencies and percentages for nominal/categorical variables. The Chi-squared test (χ^2) was used to test the association between two categorical variables and Independent Samples t Test (t) to compare means for statistical differences between INPs and PGD users.

The clinical notes review concludes by reporting an inter-rater review between the researcher with local representatives and with a pharmacist. Ten percent (n=77) of each sites' clinical notes' quota were independently checked by a local representative (this was based on the quota of notes, not the final number included). Inter-rater reliability could not be measured statistically as it was not possible to obtain a definitive decision on whose assessment was accurate as R&D permissions had expired when analysis was undertaken. Therefore, it was decided that a descriptive discussion around inter-rater reliability was more appropriate than statistical testing in this scenario. A pharmacist with specialist knowledge in HIV pharmacology reviewed a random

sample of 18 medication assessments where patients had pre-existing medical conditions, allergies and/ or concurrent medications (examples presented in Appendix II). The researcher incorporated the pharmacist's feedback within the case notes assessments. All cases or queries where errors or omissions were identified were discussed locally during data collection, and agreement was reached with the local representative.



INP= independent nurse prescribing; PGD= patient group direction(s); med= medication given; no med= no medication given

**Difference in INP notes are because Site 2's notes could not be included in frequency analysis as they could only provide attendances where medication was delivered. Eighteen notes excluded from 'INP no med' in frequency analysis as these were sourced from clinical diaries (rather than clinic attendance lists) to achieve study quotas.*

***201 notes not included in further analyses were sourced from Site 4, which were included only for frequency analysis; this occurred when the quota for Site 4 was surpassed*

Figure 5-1 Structure and sample size of clinical notes review findings

5.9 Clinical notes review: Findings

Analysis of the clinical notes/ patient presentations focussed on the appropriateness of the medication related activities within the context of individual cases. This section presents data clinical notes' inclusion/ exclusion and the frequency of medication delivery. A description of the patients for whom notes were sampled, and consultation characteristics, are then provided. An analysis of medication related activities is then presented, before concluding with an assessment of overall medication errors, appropriateness and safety, and the inter-rater comparisons findings.

5.9.1 Clinical notes inclusion/ exclusion

A total of 3,052 patient presentations were reviewed, 1,201 (39.4%) were excluded. Frequency of medication analysis included 1,851 presentations (INP=711, PGD=1,140); 201 of these records were not used in any further analysis as minimum quotas for detailed consultation analysis had been achieved (see Table 5-18). The detailed clinical records review included 1,682 (55.1%: INP=743, PGD=939) and involved 879 patient presentations where medication was given (INP med=399, PGD med=480) and a further 803 where medicines were not given (INP no med=344, PGD no med=459). Of the 1,370 patient presentations excluded from the detailed consultation review, the most frequent rationale was that patient care was delivered by staff who were not trained to prescribe or administer medicines by PGDs (n=857, 62.6%).

Medication delivery frequency

5.9.2 Frequency of medication delivery

Of all the 1,851 patient presentations (INP=711, PGD=1,140), INP was used more frequently (n=385, 54.1%) than PGDs (n=548, 48.1%: $\chi^2 = 6.47$, df = 1, p=0.011) to deliver medications.

Table 5-18 Rationale for excluding patients' notes from the clinical notes review

Clinical notes exclusion rationale (n=number of notes excluded per site)	Site 1 (n=262)		Site 2 (n=6)		Site 3 (n=92)		Site 4 (n=655)		Site 5 (n=355)		Total (n=1370)	
	n	%	n	%	n	%	n	%	n	%	n	%
Main type of clinical notes:	Paper		Electronic		Electronic		Electronic		Paper			
Non-eligible staff member	195	74.4	6	100.0	91	98.9	282	43.1	283	79.7	857	62.6
Additional data included for medication frequency only*	0	0.0	0	0.0	0	0.0	201	30.7	0	0.0	201	14.7
Administration / virtual clinic/ telephone	0	0.0	0	0.0	0	0.0	134	20.5	0	0.0	134	9.8
Unable to locate paper based notes	57	21.8	0	0.0	0	0.0	0	0.0	55	15.5	112	8.2
Episode not found in notes	10	3.8	0	0.0	1	1.1	11	1.7	17	4.8	39	2.8
Nurses' initial documentation allocating patients' to the relevant clinic for that presentation	0	0.0	0	0.0	0	0.0	27	4.1	0	0.0	27	2.0

**'Additional data included for medication frequency only' (n=201), was used in frequency analysis (n=1851), but not in patient presentations review (n=1682), as minimum quotas had been achieved*

5.9.3 Distribution of notes across research groups

Data collection continued until each category achieved the target '344' (based on sample size calculation Section 5.8.2), A total of 1,682 patient presentations (INP= INP=743, PGD=939: range 344-480 across the four categories) were included for detailed review. More than half the records related to PGD users, rather than INPs (55.8% vs. 44.2%). The proportion of notes showing medication was delivered was over 50% for both INP and PGD (see Table 5-19). A total of 29 INPs and 58 PGD users' were involved in the consultations included.

Table 5-19 Notes included in each group

Group type	INP	PGD	Total
Medication given in care episode	399 (53.7%)	480 (51.1%)	879 (52.3%)
NO medication given in care episode	344 (46.3%)	459 (49.0%)	803 (47.7%)
Total	743 (44.2%)	939 (55.8%)	1682 (100%)

INP= independent nurse prescribing, PGD= patient group directions

5.9.3.1 Patient and consultation characteristics

Over half (n=859, 51.1%) of the patient presentations reviewed were those of female patients. Overall, patients' mean age was 30 years, 73.3% (n=1,232) were 'White' and 68.1% (n=1,145) were heterosexual (see Table 5-20 for patient demographics and consultation characteristics). Across all groups, patients most frequently presented for 'new episodes of care' (n=1,149, 68.3%). There was no statistical difference between INP and PGD managing new (INP=517, 69.6%; PGD=632, 67.3%) and follow-up (INP=226, 30.4%; PGD=307, 32.7%) presentations (χ^2 = 0.794, df =1, p=0.399); however, INP were statistically more likely to manage patients presenting with symptoms than PGDs (38.4% vs. 28.1%, respectively: χ^2 = 28.443, df = 1, p<0.001).

Table 5-20 Demographics of patients included in the clinical notes review

Patients' demographics		INP (n=743)				PGD (n=939)				Total (n=1682)	
		Med (n=399)		No Med (n=344)		Med (n=480)		No med (n=459)			
		n	%	n	%	n	%	n	%	n	%
Gender	Male	150	37.6	171	49.7	223	46.5	278	60.6	822	48.9
	Female	249	62.4	173	50.3	256	53.3	181	39.4	859	51.1
	Transgender	0	0.0	0	0.0	1	0.2	0	0.0	1	0.1
Age at presentation	Range	16 to 73		16 to 66		16 to 77		16 to 87		16 to 87	
	Mean	29.5		31.7		29.8		30.6		30.2	
	Standard deviation	11.3		11.6		11.2		11.3		11.4	
Ethnic origin	White British, Irish & Other	293	73.4	247	71.8	348	72.4	344	75	1232	73.3
	Unknown	20	5	19	5.5	26	5.4	24	5.2	89	5.3
	Black African	13	3.3	19	5.5	15	3.1	19	4.1	66	3.9
	Mixed	22	5.6	12	3.5	31	6.5	22	4.8	87	5.1
	Asian & Chinese	19	4.9	18	5.3	24	5.1	19	4.1	80	4.8
	Black Caribbean & Other	12	3.1	14	4.1	24	5	18	3.9	68	4
	Other	20	5	15	4.4	12	2.5	13	2.8	60	3.6
Sexuality	Heterosexual	284	71.2	234	68.0	319	66.5	308	67.1	1145	68.1
	Homosexual	66	16.5	65	18.9	108	22.5	103	22.4	342	20.3
	Bisexual	9	2.3	16	4.7	29	6.0	29	6.3	83	4.9
	Unknown	40	10.0	29	8.4	24	5.0	19	4.1	112	6.7
Presentation type	New	288	72.2	229	66.6	323	67.3	309	67.3	1149	68.3
	Follow-up	111	27.8	115	33.4	157	32.7	150	32.7	533	31.7
	Statistical testing*	χ^2 =0.794, df = 1, p=0.399 (INP vs. PGD)									
Symptoms?	Asymptomatic	120	30.1	185	53.8	220	45.8	333	72.5	858	51.0
	Symptomatic	182	45.6	103	29.9	201	41.9	63	13.7	549	32.6
	Unknown	97	24.3	56	16.3	59	12.3	63	13.7	275	16.3
	Statistical testing*	χ^2 = 28.443, df =1, p<0.001 (INP vs. PGD)									

**Statistical testing compares INP (med and no med) with PGD (med and no med); 'Unknown' excluded from tests. INP= independent nurse prescribing, PGD= patient group directions, med= medication given, no med= no medication given, χ^2 = Chi-squared test*

5.9.4 Patient management and diagnoses in sexual health

Patients' management was categorised, by the researcher, as 'Procedural tasks' and/ or 'Diagnostic'. Within the 1,682 patient presentations there were 1,838 procedural tasks. These tasks most frequently involved sexual health screening (n=929, 50.5%), the remaining involved contraception provision (n=359, 19.5%), follow-up care (n=315, 17.1%) and specialist interventions (n=235, 12.9%: see Figure 5-2).

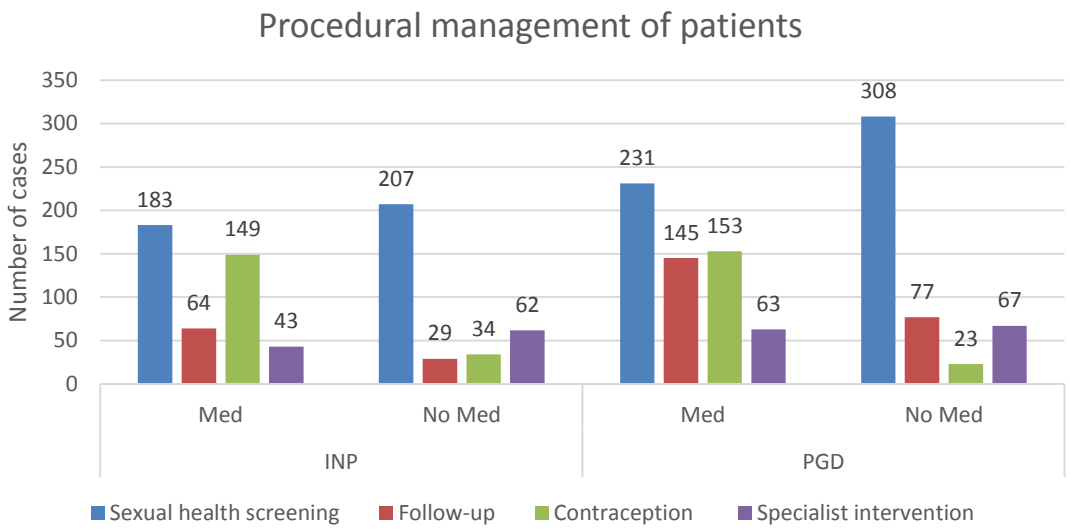


Figure 5-2 Procedural management of patients

A total of 788 diagnoses were found from the review of patient presentations. These mostly included the diagnosis of bacterial sexual infections (n=319, 40.4%); the remainder included other genital infections (n=211, 26.8%), sexual contacts of a person with an infection (n=146, 18.5%) and viral sexual infections (n=112, 14.2%: see Figure 5-3). A detailed breakdown of procedural tasks and diagnoses are presented in Appendix CC.

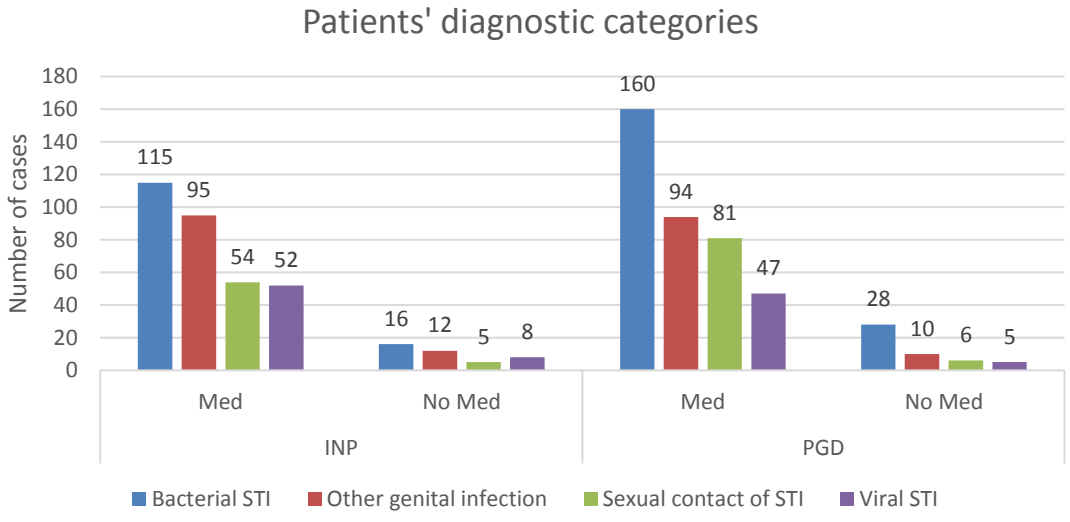


Figure 5-3 Patients' diagnostic categories

5.9.5 Autonomous practice

Of all the patient presentations reviewed (n=1,682), INPs were statistically more likely to complete episodes of care autonomously than PGD users, regardless of whether medication was delivered or not (83.0% vs. 76.0%, respectively: χ^2= 12.225, df= 1, p<0.001: see Table 5-21). When patient presentations were limited to cases where medication was delivered (n=879), both INP and PGD users were less likely to work autonomously compared to when all cases were included; however, INP were again overall more likely to complete care autonomously compared to PGD (77.7% vs. 64.2%, respectively: χ^2= 19.099, df= 1, p<0.001: see Table 5-22). A number of reasons were provided in the clinical notes by nurses for seeking advice from others, and 'obtaining medication advice' was the most frequent reason reported (n=214, 12.7%: see Table 5-23). PGD users were more likely to seek medication advice compared to INP (INP=51, 6.9%; PGD=163, 17.4%: χ^2 = 70.229, df = 1, p<0.001); however, there was no difference with regards to seeking clinical advice (INP=76, 10.2%; PGD=118, 12.6%: χ^2= 3.522, df= 1, p= 0.061).

Table 5-21 Likelihood of autonomous practice, all patient presentations (medication delivered and not delivered)

Autonomy of practice (all groups)	INP	PGD	Total
Autonomous practice	617 (83.0%)	714 (76.0%)	1331 (79.1%)
Non-autonomous practice	126 (17.0%)	225 (24.0%)	351 (20.9%)
Total	743 (44.2%)	939 (55.8%)	1682 (100%)
Statistical testing: χ^2 =12.225, df = 1, p<0.001 (INP vs. PGD)			

INP= independent nurse prescribing, PGD=patient group directions, χ^2 = Chi-squared test

Table 5-22 Autonomous practice limited to patient presentations where medication was delivered

Autonomy of practice (medication delivery)	INP	PGD	Total
Autonomous practice	310 (77.7%)	308 (64.2%)	618 (70.3%)
Non-autonomous practice	89 (22.3%)	172 (35.8%)	261 (29.7%)
Total	399 (45.4%)	480 (54.6%)	879 (100%)
Statistical testing: χ^2 =19.099, df =1, *p*<0.001 (INP vs. PGD)			

INP= independent nurse prescribing, PGD=patient group directions, χ^2 = Chi-squared test

Table 5-23 Autonomous practice frequency and reasons for nurses seeking additional professional support

Autonomous practice	INP (n=743)				PGD (n=939)				Total (n=1682)		Statistical testing** (INP vs PGD)
	Med (n=399)*		No med (n=344)		Med (n=480)*		No med (n=459)				
	n	%	n	%	n	%	n	%	n	%	
Autonomous practice	310	77.7	307	89.2	308	64.2	406	88.5	1331	79.1	
Medicine advice sought	49	10.3	2	0.6	157	32.7	6	1.3	214	12.7	χ^2 = 70.229, df =1, p<0.001
Clinical advice sought	41	12.3	35	10.2	71	14.8	47	10.2	194	11.5	χ^2 =3.522, df = 1, p=0.061

**Nurses in both 'medication delivered' groups may have sought both medicines and clinical advice*

***Statistical testing compares INP (med and no med) with PGD (med and no med) autonomous practice with 'medicine advice sought', and autonomous practice with 'clinical advice sought'.*

INP= independent nurse prescribing, PGD= patient group directions, med= medication given, no med= no medication given, χ^2 = Chi-Squared test

5.9.6 Medications delivered

From the patient presentations in which medication was delivered (n=879: INP=399, PGD=480: Table 5-19), 1,357 individual drug items were provided. This included 66 different drugs (INP=620 items comprising 56 different drugs; PGD=737 items comprising 51 different drugs. For detailed list see Appendix DD). A description of the drug groups provided is presented in Table 5-24. Drugs were grouped, by the researcher, to demonstrate how they were being used specifically within sexual health, rather than their official medication categories. Antibiotics were the most frequently delivered medicines for both INPs (n=203, 32.7%) and PGD users (n=283, 38.4%). Azithromycin was the most frequently delivered drug overall (n=231, 17.0%).

Table 5-24 Medication delivered drug categories

Drug groups* (number of different products)	INP (n=620)		PGD (n=737)		Total (n=1357)	
	n	%	n	%	n	%
Antibiotics (n=15)	203	32.7	283	38.4	486	35.8
Anaesthetics (n=2)	76	12.3	80	10.9	156	11.5
Wart treatments (n=4)	56	9.0	60	8.1	116	8.5
Vaccinations (n=3)	27	4.4	88	11.9	115	8.5
Short acting contraception (pills, patch, ring: n=8)	59	9.5	54	7.3	113	8.3
Long-acting reversible contraception (n=3)	52	8.4	53	7.2	105	7.7
Antifungals (n=4)	49	7.9	42	5.7	91	6.7
Termination of pregnancy regimens (n=4: excluding azithromycin)	30	4.8	11	1.5	41	3.0
Emergency contraception (n=2)	14	2.3	26	3.5	40	2.9
Topical creams (n=10)	11	1.8	24	3.3	35	2.6
Antiviral (n=1)	14	2.3	8	1.1	22	1.6
HIV anti-retroviral (n=4)	14	2.3	4	0.5	18	1.3
Erectile dysfunction treatments (n=4)	10	1.6	1	0.1	12	0.9
Non-steroidal anti-inflammatory drugs (n=2)	1	0.2	1	0.1	2	0.1
Total number of drugs delivered	620	100	737	100	1357	100

**Drug groups categorised to demonstrate therapeutic treatment of sexual health presentations rather than official formulary classification. INP= independent nurse prescribing, PGD=patient group directions*

5.9.7 Completeness of prescription documentation and provision of medication delivery

Of the 1,357 drug items delivered, the medicine name was clearly documented on all but one record. The remaining five components of the 'prescription' were less consistently recorded (see Table 5-25): e.g. the administration routes were only completed in care delivered by 435 (74.3%) of INP documented medicines, and 569 (77.2%) of PGD users. PGD users were statistically more likely to document the full 'prescription' compared to INP (85.5% vs. 82.5%, respectively: χ^2= 13.003, df= 1, p<0.001). Across both groups, medication was most frequently provided as pre-packed 'to-take-out' treatment packs (n=462, 34.2%) or directly administered as injections (n=417, 30.7%: see Table 5-26).

Table 5-25 Completeness of documented 'prescription' in patients' clinical notes

Prescription component:	Name		Dose		Route		Frequency		Duration		Signature		Summative score		Statistical testing (INP vs. PGD)
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	
INP (n=620)	619	99.8	513	82.7	435	70.2	462	74.5	484	78.1	557	89.3	3070 (/3720)	82.5	χ^2= 13.003, df =1, p<0.001
PGD (n=737)	737	100	612	83.0	569	77.2	578	78.4	613	83.2	670	90.9	3779 (/4422)	85.5	

INP= independent nurse prescribing, PGD=patient group directions, χ^2 = Chi-squared test

Table 5-26 Method of delivering medication

Method of medication delivery	INP (n=620)		PGD (n=737)		Total (n=1357)	
	n	%	n	%	n	%
'To take out' pre-pack medication	187	30.2	275	37.3	462	34.0
Injection	168	27.1	249	33.8	417	30.7
Not known/ missing	94	15.2	67	9.1	161	11.9
Directly observed therapy	66	10.6	80	10.9	146	10.8
Procedure	67	10.8	51	6.9	118	8.7
Collect from hospital pharmacy	22	3.5	5	0.7	27	2.0
Other	16	2.6	10	1.3	26	1.9

INP= independent nurse prescribing, PGD=patient group directions

5.9.8 Professionals who wrote prescriptions

Of the 1,357 individual medication items provided, 306 (22.5%) prescriptions were written by doctors; therefore, nurses did not practice autonomously in these episodes. As might be expected PGD users (as compared to INP) were more likely to require the support of a colleague to deliver medications (33.6% vs. 13.1%, χ^2 =77.691, df =1, p<0.001 see Table 5-27). The most common reason doctors prescribed for INP was the provision of full drug regimens for the management of termination of pregnancies (n=44/81, 54.3%: made up of 29 individual termination of pregnancy drug items and 15 azithromycin 'antibiotic' items). Nurses cannot legally prescribe termination of pregnancy drugs (Abortion Act, 1967, RCN, 2017). Azithromycin (n=26/225, 11.6%) was the most frequent drug prescribed by a doctor for PGD users. These specific cases were usually because the doctor had some form of prior involvement with patient management, rather than the PGD user stopping consultations to seek a prescription. The categories of medications prescribed by doctors are summarised in Table 5-28 (see Appendix EE for the full list of these medicines). Of the 48 actual drugs prescribed by doctors, INP had the capability to prescribed 46 (95.8%), whereas PGD users could only have supplied/ administered 27 (56.3%), due to the availability of approved PGD documents across the five sites.

Table 5-27 Professional group writing 'prescriptions'

Prescription written by	INP (n=620)		PGD (n=737)		Total (n=1357)		Statistical testing (INP vs PGD)
	n	%	n	%	n	%	
INP	539	86.9	23	3.1	562	41.4	χ^2 =77.691, df = 1, *p*<0.001
PGD			489	66.4	489	36.0	
Doctor	81	13.1	225	30.5	306	22.5	

INP= independent nurse prescribing, PGD=patient group directions, χ^2 = Chi-squared test

Table 5-28 Drug categories prescribed by doctors

Drug groups* prescribed by doctor for INP & PGD (number of specific drugs)	INP (n=81)		PGD (n=225)	
	n	%	n	%
Antibiotic (n=11)	27	32.5	89	39.5
Vaccinations (n=3)	6	7.2	33	14.7
Short acting contraception (pills n=6)	3	3.6	22	9.7
Wart treatments (n=5)	2	2.4	17	7.4
Anaesthetics (n=1)	6	7.2	13	5.8
Antifungal (n=3)	4	4.8	13	5.7
Termination of pregnancy drug regimens (n=7)	29	34.9	12	5.2
Emergency contraception (n=2)	0	0.0	8	3.5
Topical creams (n=4)	0	0.0	6	2.5
Long-Active Reversible Contraception (n=2)	1	1.2	5	2.2
HIV antiretroviral (n=2)	4	4.8	4	1.8
Antiviral (n=1)	0	0.0	3	1.3
Non-steroidal anti-inflammatory (n=1)	1	1.2	0	0.0

**Drug groups categorised to demonstrate therapeutic treatment of sexual health presentations rather than official formulary classification. INP= independent nurse prescribing, PGD=patient group directions*

5.9.9 Safety of medication provision

Across 879 patient presentations, involving the delivery of medications, patients' past medical histories (n= 816, 92.8%), concurrent medications (n= 808, 91.9%), allergies (815, 92.7%), and in the 505 female patients, the pregnancy risk (n=481, 95.2%) documentation was relatively good. Overall, INP were statistically more likely to record these details compared to PGD users (INP=1,131/1,446, 78.2%; PGD=1,308/1,696, 77.1% potential documentations: χ^2 =14.401, df =1, p<0.001: Table 5-29).

Table 5-29 Documentation of past medical history, concurrent medications, allergies and pregnancy risk

Accuracy of documented risk assessment prior to delivering medication		INP (n=399)		PGD (n=480)		Total (n=879)		Statistical testing (INP vs PGD)
		n	%	n	%	n	%	
Past medical histories	Documented	380	95.2	436	90.9	816	92.8	χ^2 =6.354, df = 1, p=0.012
	Not clearly documented	19	4.8	44	9.2	63	7.2	
Concurrent medications	Documented	374	93.7	434	90.5	808	91.9	χ^2 =3.23, df =1, p=0.072
	Not clearly documented	25	6.3	46	9.6	71	8.1	
Allergies	Documented	377	94.5	438	91.3	815	92.7	χ^2 =3.380, df = 1, p=0.066
	Not clearly documented	22	5.5	42	8.8	64	7.3	
Female patients only		**INP (n=249)**		**PGD (n=256)**		**Total (n=505)**		
Pregnancy risk	Documented	240	96.4	241	94.1	481	95.2	χ^2 =1.405, df = 1, p=0.236
	Not clearly documented	9	3.6	15	5.9	24	4.8	
Overall documentation statistical testing		χ^2 =14.401, df = 1, p<0.001 (INP vs. PGD)						

INP= independent nurse prescribing, PGD=patient group directions, χ^2 = Chi-squared test

Specific details recorded, relating to the safety of medication delivery in patients, were pregnancy, breast-feeding, liver conditions or renal disease (see Appendix FF). A total of 8.5% (43/505) of female patients were pregnant; 75% (n=33) of these were seeking termination of pregnancy. Seven female patients were breastfeeding. Six patients had liver or renal infections/ conditions. All medications provided for these patients were judged as safe and appropriate.

5.9.10 Medication appropriateness index

Five hundred and forty three (40%) of the 1,357 items of medication delivered were given to patients with a pre-existing medical condition/ allergy [*medication-disease/ condition interaction*], and/ or 538 (39.6%) who were taking concurrent medications (see Table 5-30). No difference was found between INPs and PGD users with regards to patients reporting existing medical conditions and/ or allergies (40.5% vs. 39.6%, respectively: χ^2 =0.072, df =1, p=0.789) or concurrent medications (36.8% vs. 42.1%, respectively: χ^2=3.718, df =1, p=0.054).

Across the 1,357 individual drug items, the medication appropriate index (MAI) demonstrated that both INP and PGD users consistently provided appropriate medication (Table 5-31). Overall, medication was predominantly clinically indicted and likely to be therapeutically effective for 98.5% (n=1,336/1,357) of the condition(s) managed. As each of the 1,357 medications were scored against ten individual MAI questions, the opportunity for errors could have totalled 13,570. The main issue identified through the MAI, involved documentation omissions, or data being unavailable (n=626/13,570, 4.6%). It was, therefore, difficult to fully ascertain medicines' appropriateness in these cases (Table 5-32). The main reason for 'inappropriate' categorisations (n=100/13,570, 0.7%) was related to prescription errors (n=86/100, 86%). This included one site that had inaccurate details of 'dose' and 'directions' for a metronidazole regimen in their electronic prescription template (errors in dose n=17; and directions n=17; overall 34/86, 39.5%); however, the appropriate medication pre-packs were available to supply the actual intended regimen as per local/ national guidance. Following this discovery by the researcher, steps were taken by the site to ensure the correct regimen was added to the template. Issues classified as 'intermediate' on the MAI classification (n=115/13,570, 0.8%) were mostly related to unclear documentation of whether cautions were given about potential minor drug interactions (n=53/115, 46.1%); e.g. concurrent use of azithromycin with some antidepressants may interfere with electrical cardiac signals (BNF, 2016).

Table 5-30 Number of patient with existing medical issues and/ or concurrent medication

Existing medical issues & concurrent medication	INP(n=620)				PGD (n=737)				Total (n=1,357)				Statistical testing (INP vs. PGD)
	No		Yes		No		Yes		No		Yes		
	n	%	n	%	n	%	n	%	n	%	n	%	
Pre-existing medical issue/ allergy*	369	59.5	251	40.5	445	60.4	292	39.6	814	60.0	543	40.0	χ^2 =0.072, df =1, p=0.789
Concurrent medication	392	63.2	228	36.8	427	57.9	310	42.1	819	60.4	538	39.6	χ^2 = 3.718, df =1, p=0.054

** Allergies were considered alongside pre-existing medical conditions in 'medication-disease/ condition interaction' during medical appropriateness index assessments. INP= independent nurse prescribing, PGD=patient group directions, χ^2 = Chi-squared test*

Table 5-31 Medication Appropriateness Index summary

Medication Appropriateness Index*	INP (n=620)								PGD (n=737)							
	Appropriate		Intermediate		Inappropriate		Not known		Appropriate		Intermediate		Inappropriate		Not known	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Is there an indication for the medication?	611	98.5	6	1.0	2	0.3	1	0.2	725	98.4	6	0.8	5	0.7	1	0.1
Is the medication effective for the condition?	609	98.2	8	1.3	2	0.3	1	0.2	727	98.6	6	0.8	4	0.5	0	0.0
Is the dosage correct?	543	87.6	11	1.8	11	1.8	55	8.9	687	93.2	3	0.4	14	1.9	33	4.5
Are the directions correct?	548	88.4	7	1.1	8	1.3	57	9.2	679	92.1	10	1.4	13	1.8	35	4.7
Are the directions practical?	549	88.5	6	1.0	8	1.3	57	9.2	699	94.8	5	0.7	0	0.0	32	4.3
Are there clinically significant medication interactions?	576	92.9	14	2.3	4	0.6	26	4.2	664	90.1	15	2.0	6	0.8	52	7.1
Are there clinically significant medication-disease/ condition interactions	578	93.2	11	1.8	0	0.0	31	5.0	671	91.0	9	1.2	6	0.8	51	6.9
Is there any unnecessary duplication with other medication(s)?	610	98.4	1	0.2	3	0.5	6	1.0	716	97.2	3	0.4	4	0.5	14	1.9
Is the duration of therapy acceptable?	560	90.3	6	1.0	0	0.0	54	8.7	691	93.8	10	1.4	14	1.9	22	3.0
Is this drug the least expensive alternative compared to others of equal utility?	615	99.2	1	0.2	1	0.2	3	0.5	735	99.7	2	0.3	0	0.0	0	0.0

**Percentages relate to the categorisation of 'appropriate', 'intermediate', 'inappropriate' and 'not known' in response to each individual medication appropriateness index question by INP and PGD (i.e. INP=620, PGD=737: INP= independent nurse prescribing, PGD=patient group directions)*

Table 5-32 Rationale for medication appropriateness index scores not being classified as 'appropriate'

Overall assessment (total potential issues=13,570)				Number of individual issues based on MAI questions (% of individual issue based on MAI question)									
Rationale for non-appropriateness scoring		Total	% of 13,570	Indi-cation	Effective	Dose	Dir-ections	Practical	Drug/ drug	Drug/ disease	Dupli-cation	Duration	Cost
Limited docum-entation (n=626)	Lack of documentation/ unable to access original notes	617	4.5	2 (0.3)	4 (0.6)	96 (15.6)	99 (16.0)	99 (16.0)	78 (12.6)	82 (13.3)	79 (12.8)	75 (12.2)	3 (0.5)
	Main prescription not seen	9	0.1	0 (0.0)	0 (0.0)	3 (33.3)	3 (33.3)	3 (33.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Inappro-priate (n=121)	Error in prescription	65	0.5	1 (1.5)	1 (1.5)	22 (33.8)	21 (32.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	20 (30.8)	0 (0.0)
	Rationale for treatment unknown	15	0.1	4 (26.7)	4 (26.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	7 (46.7)	0 (0.0)	0 (0.0)
	Unsafe/ inappropriate	13	0.1	2 (15.4)	2 (15.4)	2 (15.4)	0 (0.0)	0 (0.0)	4 (30.8)	0 (0.0)	0 (0.0)	3 (23.1)	0 (0.0)
	Potential moderate/ significant drug interaction	10	0.1	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	10 (100)	0 (0.0)	0 (0.0)	0 (0.0)
Intermed-iate (n=115)	Potential minor drug interaction	53	0.4	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	34 (64.2)	19 (35.8)	0 (0.0)	0 (0.0)	0 (0.0)
	Unclear treatment documentation	34	0.3	9 (26.5)	8 (23.5)	0 (0.0)	1 (2.9)	1 (2.9)	0 (0.0)	0 (0.0)	4 (11.8)	11 (32.4)	0 (0.0)
	Effectiveness of documented prescription unclear	22	0.2	3 (13.6)	1 (4.5)	3 (13.6)	3 (13.6)	3 (13.6)	0 (0.0)	0 (0.0)	0 (0.0)	5 (22.7)	4 (18.2)
	Documentation error	4	0.0	0 (0.0)	0 (0.0)	0 (0.0)	2 (50.0)	2 (50.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	Diagnostic tests not completed	2	0.0	0 (0.0)	2 (100)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

INP= independent nurse prescribing, PGD=patient group directions

Table 5-33 summarises the MAI scoring for INPs and PGD users. There was comparable medication appropriateness scoring between both groups (t = 1.032, df = 1,239.6, p=0.302). Due to the MAI's weighted scoring system (which rates appropriateness 0-18, closer to 0 more appropriate, see page 148) had all aspects been weighted as 'inappropriate' or 'not known', a total score of 24,426 (i.e. 1,357*18) would have been achieved. Both INP (582) and PGD users (602) scored very low, i.e. demonstrating a high level of appropriate medication delivery for the conditions treated. Overall, 81% of medications scored '0' (i.e. no inappropriate medication provision), with a mean score of 0.9/18.

Table 5-33 Medication Appropriateness Index weighted scoring results

Medication Appropriateness Index scoring	INP (n=620)	PGD (n=737)	Total (n=1357)
Potential highest MAI weighted score (n*18)	11160	13266	24426
Combined MAI weighted score	582	602	1184
Mean MAI weighted score (out of 18)*	0.9	0.8	0.9
Standard Deviation	2.3	2.0	2.1
Range of MAI weighted scores	0 to 14	0 to 11	0 to 14
Number scoring '0': most appropriate	505 (81.5%)	603 (81.8%)	1108 (81.7%)
Statistical testing (INP vs PGD)	t = 1.032, df = 1239.6, p=0.302** mean difference 0.1 (95% CI: -0.1 to 0.4)		

*Range 0-18, closer to 0 more appropriate. **Levene's Test equal variances not assumed. *INP= independent nurse prescribing, PGD=patient group direction, t= Independent Samples t Test*

5.9.11 Appropriateness of PGD medication delivery in clinical practice

PGD documents across the five sites demonstrated that users had access to between 11 and 37 different medications (mean per site= 20.4). Contraception provision was inconsistent across all sites. Appendix GG demonstrates the variation of medications available via PGDs.

There were 72 cases where PGDs were used inappropriately across the 480 patient presentations in which medication was delivered. An assessment of the associated clinical governance identified that appropriate clinical governance was in place for 407 (84.8%) of the 480 PGD medication delivery episodes. See Table 5-34. In 39 (40.6% of 96 errors/ omissions or 8.1% of all PGD presentations where medication was delivered) medicines were utilised outside their restrictions; however, these medicines were clinically appropriate for the patients' presentations. A further ten (2.1%) patient presentations had medication prescribed by a doctor despite a

suitable PGD being available; although not technically an error, the need to obtain a prescription was not regarded as appropriate use of the PGD (classed as intermediate accuracy).

Table 5-34 Appropriate delivery of medications using PGDs

PGD accuracy	Number (n=480)	%	Description	Frequency
Correct	407	84.8		407
Intermediate	34	7.1	Procedural, but no PGD visualised by researcher (cryotherapy=9)*	9
			Unclear clinical record documentation	11
			PGD covers, but separate prescription sought with no clear rationale why it was not delivered autonomously	10
			Medication instructions inaccurate	4
Incorrect	28	5.8	Outside PGD restrictions*	13
			Patient symptomatic, excluded from PGD*	8
			No medicinal PGD visualised (aciclovir; Daktakort; Diprobase (twice); hydrocortisone; Femodette)*	6
			PGD signed by nurse, given administered by a different nurse*	1
Limited 'prescription' documentation	11	2.3	Unclear who authorised medication delivery	9
			Brand of medicine unclear*	1
			Medication indication unclear*	1

**These were clinically safe and appropriate medication choices for the patient and condition being treated; however, were given outside the PGD restrictions or a lack of documentation makes it difficult to ascertain if the patients' presentations were included in the PGD. This constitutes 8.1% (n=39/480) of medication deliveries by PGD users. PGD= patient group direction.*

To further test the appropriateness of PGDs in clinical practice, INPs' patient presentations (n=399) were compared against local site-specific PGDs (n=480). Just under half (n=185, 46.4%) of INPs' patient presentations would not have been covered had they been governed by locally-based PGDs (n=225, 46.9%). This percentage is similar across both groups, as presented in Table 5-35. Therefore, the availability and restrictions associated with PGD documents would have directly affected INPs' practice autonomy, had they been restricted to using PGDs.

Table 5-35 Appropriateness of PGDs to manage all patient episodes

PGD clinical coverage for all patient presentations	INP (n=399)		PGD (n=480)		Total (n=879)	
	n	%	n	%	n	%
PGD covers patients' presentation	214	53.6	254	52.9	468	53.2
PGD does not cover patients' presentation	136	34.1	186	38.8	322	36.6
No PGD available for patients' presentation	49	12.3	39	8.1	88	10.0
Unable to assess	0	0.0	1	0.2	1	0.1

INP= independent nurse prescribing, PGD=patient group direction

5.9.12 Where no medication was delivered, was this appropriate?

From the 1,357 patient presentations reviewed, there were incidences were medication was 'potentially' (n=19, 1.1%) or 'specifically' (n=25, 1.5%) indicated, for which there was no documentation that is was offered or given (see Table 5-36). This most commonly related to failure to offer appropriate prophylactic medications (n=14/25, 56.0% or 0.8% overall: Table 5-37). There were a further 101 incidences in which the documentation highlighted that despite medication being indicated, the nurse appropriately did not provide any (see Table 5-38). This was most commonly because the required medication required was not within the sexual health remit, and so patients were signposted to alternative appropriate services (n=24, 2.8%). Another reason for this lack of provision was that the contacts of people with sexual infections declined treatment, preferring to wait for their results rather than accept STI prophylactic treatment (n=20, 2.3%).

Table 5-36 Appropriate non-provision of medication

Non-provision of medication	INP (n=743)				PGD (n=939)				Total (n=1682)	
	Med (n=399)		No med (n=344)		Med (n=480)		No med (n=459)			
	n	%	n	%	n	%	n	%	n	%
Medication not indicated	9	2.3	333	96.8	12	2.5	448	97.6	802	47.7
Medication potentially indicated	5	1.3	6	1.7	4	0.8	4	0.9	19	1.1
Medication indicated, but not given/ documented	5	1.3	5	1.5	8	1.7	7	1.5	25	1.5

INP= independent nurse prescribing, PGD=patient group direction

Table 5-37 Medication inappropriately not provided/ offered/ documented by nurses

Treatment not given despite being indicated	INP		PGD	
	Med	No med	Med	No Med
Appropriate prophylaxis medication not offered (e.g. emergency contraception, post exposure prophylaxis for sexual exposure, vaccination, sexual contact)	1	3	4	6
Clinical presentation indicates treatment was indicated (i.e. pelvic inflammatory disease, warts, bacterial vaginosis, proctitis, balanitis)	3	2	2	1
Incorrect clinical management resulting in medication inappropriately not being given	1	0	1	0
Doctor advised to give medication, no documentation that it was delivered	0	0	1	0

INP= independent nurse prescribing, PGD=patient group direction

Table 5-38 Medication indicated or acknowledged but appropriately not given

Medication not given, but correctly acknowledged/ offered by nurse	INP (n=743)		PGD (n=939)	
	n	%	n	%
Treatment not indicated/ appropriate for sexual health setting	9	1.2	15	1.6
Patient would prefer to wait for results before being treated	6	0.8	14	1.5
Patient declined or nurse appropriately discontinued hepatitis B vaccine prescription	9	1.2	10	1.1
Already taking the appropriate treatment	6	0.8	9	1.0
Patient offered and declined emergency contraception	5	0.7	6	0.6
Patient offered and declined other treatments	5	0.7	5	0.5
Patient was clinically managed by another, nurse didn't need to deliver medication	2	0.3	0	0.0

INP= independent nurse prescribing, PGD=patient group direction

5.9.13 Unplanned repeat consultations for index condition or non-attendance to follow-up

Of the 1,682 patient presentations reviewed, 306 (18.2%) patients returned within three months for 400 specific issues (Table 5-39). The reasons for returning were relatively consistent across INP and PGD users (were medication was and was not given). There were 15 different reasons categorised under four headings (Table 5-40). There was no indication that any of these reasons were because nurses used INP or PGDs. The only difference between patients of INPs and PGD users', relating to follow-up, was that INPs' patients were more likely not to attend expected follow-up, compared to PGD users (9.6% vs. 2.4%, respectively: χ^2 =8.890, df =1, p=0.003).

Table 5-39 Unexpected re-attendance rates

Unexpected re-attendance	INP (n=399)		No INP (n=344)		PGD (n=480)		No PGD (n=459)		Total (n=1682)	
	n	%	n	%	n	%	n	%	n	%
Number of patients who didn't re-attend	308	77.2	290	84.3	387	80.6	391	85.2	1376	81.8
Number of patients re-attending	91	22.8	54	15.7	93	19.4	68	14.8	306	18.2
Number of individual return rationales*	135		65		125		75		400	

**patients can return for multiple rationales. INP= independent nurse prescribing, PGD= patient group directions, med= medication given, no med= no medication given*

Table 5-40 Rationales for re-attending

Rationale for unexpected return	Total INP sample= 743				Total PGD sample= 939				Statistical testing** Attendance vs. re-attendance	Total (n=306)	
	INP (n=91)		No INP(n=54)		PGD (n=93)		No PGD (n=68)				
	n	%	n	%	n	%	n	%		n	%
Clinical/ diagnostic issue that was not known at initial visit (INP=99; PGD=101)**											
Positive test from diagnostics	25	27.5	17	31.5	35	37.6	25	36.8	χ^2 =2.611, df =1, p=0.106	102	33.3
Developed new genital symptoms	19	20.9	6	11.1	11	11.8	1	1.5		37	12.1
Repeat testing indicated/ required	10	11.0	5	9.3	4	4.3	8	11.8		27	8.8
New sexual health issue (non-symptomatic)	2	2.2	8	14.8	4	4.3	3	4.4		17	5.6
Low Hepatitis titre, booster/ course required	3	3.3	4	7.4	1	1.1	9	13.2		17	5.6
Symptomatic or adverse issues that became apparent after initial visit (INP=59; PGD=56)**											
Symptoms not resolved/ worsened/ returned	14	15.4	2	3.7	10	10.8	8	11.8	χ^2 =2.545, df =1, p=0.111	34	11.1
Drug/ contraception side effects	16	17.6	4	7.4	10	10.8	1	1.5		31	10.1
Long-acting reversible contraception follow-up issues	5	5.5	5	9.3	7	7.5	3	4.4		20	6.5
Wart treatment ineffective/ prolonged/ changed	6	6.6	1	1.9	10	10.8	2	2.9		19	6.2
High risk sexual behaviour/ psychosocial support	5	5.5	1	1.9	1	1.1	4	5.9		11	3.6
Behavioural or processing issue which potentially could have been avoided (patients' behaviour was large component) (INP=28; PGD=39)**											
Re-treatment for same condition	11	12.1	0	0.0	21	22.6	0	0.0	χ^2 =0.150, df =1, p=0.698	32	10.5
Recalled due to service processing issues	3	3.3	6	11.1	2	2.2	7	10.3		18	5.9
Partner notification/ sexual contact issues	1	1.1	1	1.9	5	5.4	2	2.9		9	2.9
Subsequent/ repeat termination of pregnancy	4	4.4	2	3.7	2	2.2	0	0.0		8	2.6
Unexpected non-attendance to follow-up (did not attend) (INP=14; PGD=4)**											
Did not attend expected follow-up	11	12.1	3	5.6	2	2.2	2	2.9	χ^2 =8.890, df =1, p=0.003	18	5.9
Total individual return rationales*	135		65		125		75			400	

**patients could return for multiple rationale (hence why overall statistical testing not completed); **Statistical testing compares INP (med and no med) with PGD (med and no med), combined into the four categories prior to testing. INP= independent nurse prescribing, PGD= patient group directions, med= medication given, no med= no medication given, χ^2 = Chi-squared test*

5.9.14 Medication error categories and rates

A total of 1,844 (error rate=8.5%) individual information omissions or errors were identified throughout the full review of patient presentations (INP=879, 47.7%; PGD=965, 52.3%). Where error categories were identified, INPs were statistically more likely to make an error/ omission compared to PGD users (9.2% vs. 7.9%, respectively: χ^2=10.418, df = 1, p=0.001). Twelve of the 17 error categories related to documentation omissions (see Table 5-41). The majority of errors were categorised as minor (INP=489, 55.6%; PGD=602, 62.4%); however, errors made by INPs as compared to PGD users were statistically more likely to be categorised as moderate severity (44.1% vs. 37.4%, Fisher's Exact Test=8.805, p=0.007: see Table 5-42). There was no evidence any patients were harmed based on the subsequent clinical documentation.

Table 5-41 Medication error categories and rates

Error categories (source of error)*	INP (n=399, 743 or 620)*			PGD (n=480, 909 or 737)*			Total (n=879, 1652 or 1357)*		
	Total potential errors (n)	Actual errors (n)	Error rate (%)	Total potential errors (n)	Actual errors (n)	Error rate (%)	Total potential errors (n)	Actual errors (n)	Error rate (%)
Route missing (prescription)**	620	185	29.8	737	168	22.8	1357	353	26.0
Administration frequency incorrect/ missing (prescription/ MAI)	620	147	23.7	737	158	21.4	1357	305	22.5
Duration not clearly documented (prescription)	620	130	21.0	737	124	16.8	1357	254	18.7
Strength/dose not clearly documented (prescription)	620	113	18.2	737	125	17.0	1357	238	17.5
Method of drug supply not clearly documented (prescription)***	620	116	18.7	737	67	9.1	1357	183	13.5
No signature on ‘prescription’ (prescription)	620	63	10.2	737	67	9.1	1357	130	9.6
Concurrent medication not clearly documented (safety)****	399	25	6.3	480	46	9.6	879	71	8.1
Allergy not clearly documented (safety)	399	22	5.5	480	42	8.8	879	64	7.3
Past medical history not clearly documented (safety)****	399	19	4.8	480	44	9.2	879	63	7.2
Outside PGD restrictions (PGD appropriateness)	0	0	0.0	737	39	5.3	737	39	5.3
Pregnancy risk assessment not clearly documented (safety)****	249	9	3.6	256	15	5.9	505	24	4.8
Medication indicated, but not given/ offered/ documented (synthesis)	743	21	2.8	909	23	2.5	1652	44	2.7
Prescription error (MAI)	620	12	1.9	737	19	2.6	1357	31	2.3
No indication for drug (MAI)	620	9	1.5	737	12	1.6	1357	21	1.5
Consideration of drug interactions not clearly documented (MAI)****	399	4	1.0	480	6	1.3	879	10	1.1
Duplication of medication (MAI)	399	3	0.8	480	4	0.8	879	7	0.8
Clinical contra-indication (MAI)	399	1	0.3	480	6	1.3	879	7	0.8
Product/ formulation not clearly documented (prescription)	620	5	0.8	737	3	0.4	1357	8	0.6
Overall error rates	**9586**	**879**	**9.2**	**12152**	**965**	**7.9**	**21738**	**1844**	**8.5**
Statistical testing (INP versus PGD)	χ^2=10.418, df= 1, p= 0.001								

Medication categories where no errors were made were not included in this analysis. **route includes all prescriptions that had missing route regardless of whether there was only one type of formulation (excluding inter-uterine devices, contraceptive implants and cryotherapy).*supply of drug relates to how patients received it (for example as a pre-pack in the clinic or from*

*pharmacy) ****these prescribing errors may not have been considered as prescribing errors in comparable studies, but as they relate to prescribing safety were included in this study. This may influence comparability in the discussion. INP= independent nurse prescribing, PGD= patient group directions, MAI= Medication Appropriateness Index, χ^2 = Chi-squared test*

Table 5-42 Categorisation of error severity

Severity based on mean scores*	INP (n=879)		PGD (n=965)		Statistical tests	Total (1844)	
	n	%	n	%		n	%
Minor (0 to <3: very unlikely to have any adverse effects)	489	55.6	602	62.4	Fisher's Exact test 8.805, p=0.007	1091	59.2
Moderate (3 to <7: likely to cause some adverse effects or interfere with therapeutic goals but very unlikely to result in death or cause lasting impairment)	388	44.1	361	37.4		749	40.6
Severe (7-10: likely to cause death or lasting impairment)	2	0.2	2	0.2		4	0.2

*INP= independent nurse prescribers, PGD=patient group direction. *Each unique error was graded 0-10 for severity by five individual raters, a mean score calculated and used to categorised error frequencies as minor, moderate or severe, in-line with Dean & Barber (1999)*

5.9.15 Assessment of safety and appropriateness of care for patient presentations

Each patients' care episode was assessed for appropriateness (appropriate, intermediate or not known) and safety (safe, unsafe or not known). The overall safety and appropriateness was then categorised in three ways: 'safe & appropriate', 'not safe and/ or appropriate', and 'not known'. Across INPs and PGD users (with and without medication delivery, n=1,682) most episodes of care were assessed, by the researcher, to be predominantly 'safe and appropriate' overall (n=1,596, 94.9%: Table 5-43). INPs were found to provide significantly more appropriate care than PGD users (INP=714, 96.1%; PGD=883, 94.0%: Fisher's Exact Test, $p<0.001$). The difference in appropriateness of care provision, was as a result of the provision of clinically appropriate care by PGD users, however medication was delivered outside of the PGDs' restrictions (n=39/43, 90.7%). There was no significant difference in the safety of care provided between groups (INP=713, 96.0%; PGD=927, 98.7%: Fisher's Exact Test, $p=0.554$). Nevertheless, INPs had higher frequencies of errors, being classed as 'moderate' severity compared with PGD users (44.1% vs. 37.4%; Fisher's Exact Test, $p=0.007$). Only a very small minority of care episodes were deemed to be 'unsafe and inappropriate' (n=8, 0.4%: Box 5.3; INP=4, PGD=4), with four errors (INP=2; PGD=2) being classed as 'severe'.

Box 5.3: The eight cases of unsafe/ inappropriate practice involved:

1. Potential drug interaction with 'antihypertensive'. If this was ketanserin, when given with azithromycin could potentially cause fatal torsade de pointes arrhythmia [mean severity score 7.4; INP]
2. Incorrect transcription of results in clinical records, resulting in delivery of incorrect treatment. The error was subsequently discovered by a local health care practitioner, the patient was informed, recalled and the correct results and treatment was issued. (INP)
3. Two patient samples were attributed to the wrong patients. This was identified by a local health care practitioner, investigated and resolved. (INP)
4. It was not documented that a patient, at high risk of HIV, had been offered post-exposure prophylaxis (PEP). The patient attended follow-up as planned, and was found to be HIV positive, therefore the PEP would have been ineffective in this situation [mean severity score 7.4:INP].
5. A patient was given the combined oral contraception pill when the risks outweighed the benefits as diastolic blood pressure was slightly over 90 (UKMEC3: Risks outweigh the benefits (FSRH, 2016)) [mean severity score 7.4: PGD].
6. Patient given high dose penicillin (benzylpenicillin 2.4MIU) with documentation of penicillin allergy [mean severity sore 7.2: PGD)
7. A PGD user signed for a drug but it was issued to the patient by another nurse.
8. A symptomatic sexual contact of gonorrhoea was not offered treatment at presentation, in line with local and national guidelines. (PGD)

While some of these issues had the potential to cause harm, there was no indication of adverse effects.

INP= independent nurse prescribing, PGD=patient group direction

Table 5-43 Overall categorisation of safe and appropriate medication delivery

Appropriateness, Safety & Overall Assessment		INP (n=743)				PGD (n=939)				Total (n=1682)		Statistical testing* (INP vs. PGD)
		Med (n=399)		No Med (n=344)		Med (n=480)		No Med (n=459)				
		n	%	n	%	n	%	n	%	n	%	
Appropriate	Appropriate	372	93.2	342	99.4	426	88.8	457	99.6	1597	94.9	Fisher's Exact Test p<0.001
	Inappropriate	1	0.3	1	0.3	42	8.8	1	0.2	45	2.7	
	Not known	26	6.5	1	0.3	12	2.5	1	0.2	40	2.4	
Safety	Safe	372	93.2	341	99.1	469	97.7	458	99.8	1640	97.5	Fisher's Exact Test p=0.554
	Unsafe	1	0.3	2	0.6	2	0.4	0	0.0	5	0.3	
	Not known	26	6.5	1	0.3	9	1.9	1	0.2	37	2.2	
Overall	Safe and appropriate	372	93.2	341	99.1	426	88.8	457	99.6	1596	94.9	Fisher's Exact Test p<0.001
	Not safe and/ or appropriate	1	0.3	2	0.6	42	8.8	1	0.2	46	2.7	
	Not known	26	6.5	1	0.3	12	2.5	1	0.2	40	2.4	

**Statistical testing compares INP (med and no med) with PGD (med and no med). Excludes 'Not known'*
INP= independent nurse prescribing, PGD= patient group directions, med= medication given, no med= no medication given

5.9.16 Interrater reliability and validity assessments

Clinical record assessments

Seventy-seven patient presentation assessments from the clinical notes were made by local representatives, to independently compare against the researcher's interpretation. Across 'demographics' and 'presentation' sections, there were high levels of agreement (see Table 5-44). The main disagreement related to the presence of symptoms (agreement=70/77 clinical records, 90.9%). Locally, particularly for contraception services, no documentation of genital symptoms indicated the patient was asymptomatic; however, as the researcher could not see any documentation this was recorded as 'not known'. Within the 'MAI' assessments, the reviewers were confident they understood the prescription regimens when assessing documentation; however, the researcher detailed that if the drugs' dose, directions or duration or the patients' past medical history or concurrent medication was not documented, a full assessment against the MAI could not be made. This represented a difference of opinion between the researcher and local representatives. These documentation issues accounted for the differences in agreement for 'overall assessment'.

A total of 161 (9.6%: see Table 5-45) further care episodes were discussed with a local representative to support conclusions.

Pharmacist random review of medication assessments

In 15/18 (83.3%) cases, the pharmacist completely agreed with the researcher. Two further episodes had slight differences in the assessment relating to concurrent HIV medications and use of antibiotics - the pharmacist identified one episode with insufficient documentation to make a full assessment, and in another case, highlighted a potential drug interaction that had a low evidence base. The final case involved advising the patient about when to take medication with concurrent use of multi-vitamins. An example of the assessment is presented in Appendix II.

Table 5-44 Inter-rater assessment between researcher and local representative

Agreement between researcher and local representative across 77 clinical records	Agreement (n=77)	
	n	%
Demographics		
Gender	77	100
Age	77	100
Ethnic origin	76	98.7
Sexual orientation	77	100
Presentation		
Episode type	77	100
Symptoms present	70	90.9
Medical history documentation	76	98.7
Concurrent medication documentation	76	98.7
Allergy documentation	75	97.5
Pregnancy risk (n=46)	45	97.8
Diagnosis	76	98.7
Medication regimen	77	100
Medication Appropriateness Index		
Indication	77	100
Effective	77	100
Dosage	67	87.0
Directions correct	68	88.3
Directions practical	71	92.2
Drug-drug interactions	73	94.8
Drug-disease interactions	72	93.5
Unnecessary duplication	76	98.7
Duration of treatment	71	92.2
Cost	75	97.5
Overall assessment		
Appropriate	67	87.0
Safe	72	93.5
Safe & appropriate	71	92.2

Table 5-45 local clarification of clinical queries, safety and appropriateness

Local clarification on individual episodes	INP (n=743)				PGD (n=939)				Total (n=1682)	
	Med (n=399)		No med (n=344)		Med (n=480)		No med (n=459)			
	n	%	n	%	n	%	n	%	n	%
No clarification required	339	85.0	330	95.9	405	84.4	447	97.4	1521	90.4
Local clarification obtained	60	15.0	14	4.1	75	15.6	12	2.6	161	9.6

INP= independent nurse prescribing, PGD= patient group directions, med= medication given, no med= no medication given

5.10 Clinical observations: Task-specific methods

5.10.1 Purpose

Building observations into the study was undertaken to consolidate data collected from the preceding stages, and assess how organisational governance, staff expertise, policies and documentation influences clinical practice. Moreover, it facilitated an understanding of the nurse-patient interaction during medication consultations that would be impossible to achieve from clinical records or questionnaires.

5.10.2 Method design

Observations are a suitable method for investigating nurse-patient interactions, communication and clinical performance (Parahoo, 2006). The observational study involved the researcher observing, audio recording and taking field notes of consultations where nurses delivered medication. Video-taping the observations would have facilitated exploration of subtleties missed during physical observation of consultations, and allow thorough critique of the researchers' conclusions. However, as sexual health involves discussing intimate and personal issues, and patients had limited time to consider participation, it was decided by the researcher, the supervisors and the REC, that audio recording was more suitable and ethical (HRA, 2015).

The Prescribing Framework (RPS, 2016) details that prescribing involves assessing the patient, considering treatment options and reaching a shared decision based on the associated governance, before prescribing can occur. The observational study was designed to determine if this process occurred in practice. Field notes (Appendix O) were made based on an earlier version of the Prescribing Framework (NPC, 2012), and the analysis utilised the updated version (RPS, 2016). Both frameworks were designed to underpin prescribing practice with a common set of multi-professional competencies. The framework's competencies were designed to support safe, effective prescribing which benefited patients' medication outcomes. Centred on the patient, 'the consultation' and 'prescribing governance', domains had ten separate dimensions (see Table 5-46) that those delivering medications should demonstrate during consultations (RPS, 2016).

Based on the data collection methods employed during observations, it was only practical to assess nurses against the 46 competencies under 'the consultation' domain. There are multiple other tools and methods available to explore healthcare consultations; however, to ensure this study remained focussed on the medication delivery aspect, only the prescribing framework (NPC, 2012; RPS, 2016) was used.

Table 5-46 Competency framework for prescribers' dimensions

The consultation	Prescribing governance
1. Assess the patient	7. Prescribe safely
2. Consider the options	8. Prescribe professionally
3. Reach a shared decision	9. Improve prescribing practice
4. Prescribe	10. Prescribe as part of a team
5. Provide information	
6. Monitor and review	

(RPS, 2016)

To further keep data collection and analysis components manageable within the study's resources, the researcher and supervisors identified that undertaking multiple observations on a small number of nurses would be the most appropriate design. This had the benefit of recruiting fewer nurses, and allowed the participants to become more comfortable with the researcher's presence. Three INPs, and three PGD users each had a quota of five medication consultations observed, totalling 30 observations. Short sessions, suitable for each nurse, were adopted to reduce observation fatigue and impact on service delivery. In order to reduce the number of unnecessary observations, participants were asked to select clinics in which they most frequently provided medication. While this may add bias, the purpose was to determine the interaction between nurses and patients during medication consultations. To support deeper analysis and triangulation, while remaining focussed on medication delivery, the observations were linked to preceding methods: i.e. the clinical diary, clinical notes review and patient experience questionnaire.

5.10.3 Recruitment

5.10.3.1 Nurses

All nurses who participated in the clinical diary across all five sites were invited to participate in the observational study. The first three INP and three PGD users who volunteered and met the

inclusion criteria (Table 4-4 on page 92 in 'Chapter 4: Methods') were selected. After volunteering, staff were given a minimum of 48 hours to read participant information sheet and consider their participation (Appendix P) and sign consent forms (Appendix Q). Two copies of the consent forms were signed, one for the participant and one for the research file. Observations took place at dates and times that were mutually suitable for the researcher and the nurse participants. Once the observer had observed and audio-recorded five consultations in which individual nurses delivered medication, recruitment for that nurse ceased.

5.10.3.2 Patients

Recruitment of patients was more complex as they had limited time to consider participation, thus making the validity of their consent an issue. Sexual health's open access episodic nature made it difficult to predict patients' attendance or which staff member would manage their care. Therefore, the researcher followed closely the Health Research Authority's (HRA, 2015) advice and the REC to ensure appropriate measures were in place to protect patient participants. Where possible, patient participant information sheets (PIS: English version Appendix R, Welsh version Appendix S) and consent forms (English version Appendix T, Welsh version Appendix U) were distributed in reception areas to all patients who were likely to be managed by the nurse participants. Based on PPI feedback, these sheets were shortened to support reading in a shorter time period (see section 4.6 on page 91). Posters advertising the study (Appendix V) were placed in waiting rooms when the observational study was actively recruiting. This allowed additional time for patients to consider participation.

At the beginning of the consultation nurse participants asked patients (in the absence of the researcher) if they would be willing to participate. This was to avoid coercion. Patients were advised that participation was voluntary and their care would not be affected if they declined this invitation. If the patient declined, the nurse continued with the consultation as normal. If the patient accepted, the nurse summoned the researcher who discussed the study, ensured patients' questions were answered satisfactorily and obtained two signed copies of the consent form. The patient and the nurse were advised they could terminate participation at any point without providing a reason. Both the nurse and the patient also had up to 48 hours after the consultation to withdraw consent, permitting additional time for patients to consider participation. If consent

was withdrawn all data collected would have been destroyed as NHS confidential waste. If during the consultation the patient appeared visibly uncomfortable, distressed or presented safeguarding/ vulnerability issues (e.g. child protection, sexual assault), the researcher had arranged with the nurse to terminate observations. These aspects were added to ensure the study did not negatively impact on patients' care. No nurse or patient withdrew their consent during or after observations.

5.10.4 Data collection

The initial data collection plan was to invite all patients managed by the nurse to participate. When it became apparent within the consultation that no medication would be required, the researcher terminated observations at an appropriate juncture. Audio-recordings were deleted, but consent forms kept. To avoid inappropriate observations, efforts were made to attend clinics more likely to deliver medication. The process became more streamlined when nurse participants first enquired why the patient had attended. If medication delivery was likely, then the nurse enquired if the patient would consider participation. Recruitment of patients was found to be easier in contraception clinics or follow-up treatment clinics than in those presenting for new episodes of GUM care.

While the researcher endeavoured not to influence practice, their presence, and the participants' awareness of audio-recording, was likely to have modified behaviour, i.e. the Hawthorne Effect. Changed behaviour is, however, difficult to maintain for extended durations (Parahoo, 2006; Moule and Goodman, 2009). The use of multiple consultations with nurses aimed to reduce the Hawthorne Effect, allowing nurse participants to get used to the observations. Nevertheless, short sessions suitable to nurses' commitments were adopted to reduce observation fatigue and impact on service delivery. The researcher did not intervene in consultations; however, they were aware of their ethical duty to stop unsafe or inappropriate practice should it have occurred. During the observations, the researcher filled out field notes and completed the clinic diary. At the end of the consultation patients were asked to complete the patient questionnaire. The patient was provided with the opportunity to ask any questions they may have had about the research prior to their leaving the clinic.

During data collection, all participants' identities were kept anonymous, replaced with study numbers and/ or pseudonyms, except on the consent form. Audio-recording staff or patients' names was avoided where possible. Transcribing was undertaken by an NHS approved transcriptionist. Patient/ staff names or site names used during consultation dialogues were removed immediately after receiving the transcripts. Original unedited transcripts were not shared with anyone else.

5.10.5 Analysis

The findings for the observational study are split into Section A and Section B. Section A presents the findings from direct observations and researcher-completed clinical diary, Section B presents data yielded from the clinical notes and patient experience questionnaires.

Under Section A, consultation characteristics were recorded in terms of patient demographics, presentation type, consultation length, attendance reason, diagnosis and medication given. Data are presented as number, percentages, mean, standard deviation and range where applicable. Chi-squared tests were used to compare categorical data, and the Independent Samples t Test was used to compare means.

Transcription of audio recordings did not commence until a minimum of 48 hours had elapsed from the end of the consultation. Each consultations' audio-recording and transcript was assessed against the 46 individual competencies from the Prescribing Framework (RPS, 2016). There was no specific scoring or weighting presented by RPS (2016); therefore, within this study to explore potential differences in practice between INPs and PGD users, a mean competency scoring system was used. Against each competency the transcripts were marked as 'not achieved' (scoring 0), 'achieved' (scoring 1), 'implied' competency (i.e. not directly observed, scoring 1) or 'not applicable' (scoring 1). Individual scores were totalled, the overall mean was calculated and compared to the potential top score of 46. Findings on the competencies achieved are presented as descriptive data. One of the researcher's supervisors who is an expert in non-medical prescribing and has used a similar tool before, independently checked four transcripts (26.7%) and agreed with the researcher's assessments. Inherent within these assessments was

compliance with local and national guidelines to ensure appropriate management of sexual health presentations.

Section B offered a deeper analysis of the observations by incorporating the clinical diary (see page 136), clinical notes review (page 143) and patient experience questionnaire (page 209) to support triangulation with other aspects of the study. Observational data were analysed as per the relevant method.

5.11 Clinical observations: Findings

The observational study's findings are presented under two distinct sections. Section A presents the direct observations based on the consultation characteristics and the prescribing framework. Section B integrates the clinical notes review and patient satisfaction questionnaire (used in the wider study) to support deeper observation analysis.

Section A:

5.11.1 Characteristics of nurse-patient consultations

Thirty nurse-patient medication delivery consultations were observed (INP=15; PGD=15) involving five INP and six PGD nurses. One PGD nurse participant withdrew, but requested their observation (n=1) was included; a sixth PGD nurse completed the four remaining observations to achieve the study's quota. Seventeen consultations involved management of genitourinary conditions (56.6%), 12 (40.0%) provided contraception only and one (3.3%) integrated both. Consultation characteristics are summarised in Appendix JJ.

There was no difference in the overall mean consultation length between INPs and PGD users (mean 19.9 vs. 16.9 minutes, respectively: t= 0.906, df= 28, p= 0.373), despite an overall mean difference of 3.0 minutes, see Table 5-47.

Table 5-47 Consultation lengths

Consultation times (minutes)	INP			PGD			Total (n=30)
	New (n=8)	Follow-up (n=7)	Total (n=15)	New (n=9)	Follow-up (n=6)	Total (n=15)	
Range	13 to 44	5 to 30	5 to 44	8 to 35	7 to 27	7 to 35	5 to 44
Total consultation time	180	118	298	171	83	254	552
Mean	22.5	16.9	19.9	19	13.8	16.9	18.4
Standard Deviation	9.8	8.1	9.2	8.9	7.6	8.5	8.8
Statistical testing*	t = 0.906, df = 28, p = 0.373 mean difference 2.9 (95% CI: -3.7 to 9.6)						

** Statistical testing compared total mean consultation lengths of INP with PGD users.*
INP = independent nurse prescribing, PGD= patient group direction, t = Independent Samples t Test, CI= confidence interval

5.11.2 Patient demographics

Approximately two thirds of patients were female (n=19, 63.3%). INPs managed an equal gender split, whereas, PGD nurses managed more females (n=11, 73.3%). Patients' mean age was 27 years. INP had equal split of heterosexual and homosexual patients (both n=7, 46.7%), whereas PGD users' managed mostly heterosexual patients (n=11, 73.3%). Consultations consisted of 17 (56.7%) new care episodes and 13 (43.3%) follow-up in total, and most patients were asymptomatic (n=21, 70.0%).

Table 5-48 Patient demographics

Patients' demographics		INP (n=15)		PGD (n=15)		Total (n=30)	
		n	%	n	%	n	%
Gender	Male	7	46.7	4	26.7	11	36.7
	Female	8	53.3	11	73.3	19	63.3
Age at presentation	Range	16 to 53		16 to 45		16 to 53	
	Mean	27.7		28.1		27.9	
	Standard deviation	10.5		9.2		9.7	
Ethnic origin	White British	8	53.3	8	53.3	16	53.3
	Unknown	2	13.3	5	33.3	7	23.3
	Black Caribbean	1	6.7	1	6.7	2	6.7
	Mixed White Caribbean	1	6.7	1	6.7	2	6.7
	Asian Pakistani	1	6.7	0	0.0	1	3.3
	White Other	1	6.7	0	0.0	1	3.3
	Other	1	6.7	0	0.0	1	3.3
Sexuality	Heterosexual	7	46.7	11	73.3	18	60.0
	Homosexual	7	46.7	0	0.0	7	23.3
	Bisexual	1	6.7	2	13.3	3	10.0
	Unknown	0	0.0	2	13.3	2	6.7
Presentation	New	8	53.3	9	60.0	17	56.7
	Follow-up	7	46.7	6	40.0	13	43.3
Symptoms	Asymptomatic	10	66.7	11	73.3	21	70.0
	Symptomatic	5	33.3	4	26.7	9	30.0

INP = independent nurse prescribing, PGD= patient group direction

5.11.3 Assessment of consultations against the prescribing framework

The prescribing framework has 46 individual competencies (RPS, 2016). INPs demonstrated a mean score of 44.7/46 and PGD users 45.4/46. There was no difference between INPs and PGD users in performance measured against the prescribing framework (Mann Whitney U= 94.500, p=0.407: Table 5-49). Detailed observational assessments against the prescribing framework are shown in Appendix KK.

Across the 30 observations, nurses frequently demonstrated that they achieved the competencies in 'Section 3: Reach a shared decision' (sub-competencies= 6) and 'Section 5: Provide information' (sub-competencies= 5). These sections were directly observed by the researcher more often in the PGD group (Section 3: n=90/90, 100%; Section 5: n=70/75, 93.3%) than INP (Section 3: n=87/90, 96.7%; Section 5: n=62/75, 82.7%); however, there was no statistical difference (Section 5: Mann Whitney U= 2,662.500, p=0.230). Despite 'Competency 1: Assess the patient' ranking third across the six prescribing framework competencies in terms of direct observation, nurses in all consultations were clearly observed taking appropriate histories, clinical assessments and interpreting / using relevant investigations.

Not all aspects of the prescribing framework components were applicable to all consultations/ presentations. For example, competency "1.7: Reviews adherence to and effectiveness of current medicines" applied to 10 contraception and three genitourinary consultations. However, sexual health nurses were not necessarily qualified to determine medication adherence for eight patients' pre-existing medical conditions. Moreover, eight further patients were not on any other medications to measure adherence. Therefore, throughout the competency assessment 'not applicable' was not negatively marked.

Other competencies, while not being directly observed, were obviously inherent within nurses' knowledge and skill base. For example, competencies "2.7: Identifies, accesses, and uses reliable and validated sources of information and critically evaluates other information" and "2.8: Stays up-to-date in own area practice and applies the principles of evidence-based practice…" were consistently demonstrated by nurses when making medication decisions based on current national/ local guidance. In these cases nurses were not specifically observed undertaking the competency by the researcher, but they were clearly 'implied' within their clinical decision making. These were considered as observed (but presented separately in Appendix KK).

Table 5-49 Summary of Prescribing Framework scores

Competency (number of subsections)	Total points*	INP (n=15)								PGD (n=15)							
		Observed		Implied		Not observed		Not applicable		Observed		Implied		Not observed		Not applicable	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
1: Assess the patient (8)	120	96	80.0	0	0.0	1	0.8	23	19.2	99	82.5	0	0.0	0	0.0	21	17.5
2: Consider the options (10)	150	68	45.3	57	38.0	1	0.7	24	16.0	72	48.0	55	36.7	0	0.0	23	15.3
3: Reach a shared decision (6)	90	87	96.7	0	0.0	0	0.0	3	3.3	90	100	0	0.0	0	0.0	0	0.0
4: Prescribe (13)	195	110	56.4	41	21.0	6	3.1	38	19.5	116	59.5	36	18.5	0	0.0	43	22.1
5: Provide information (5)	75	62	82.7	0	0.0	8	10.7	5	6.7	70	93.3	0	0.0	4	5.3	1	1.3
6: Monitor and review (4)	60	39	65.0	0	0.0	0	0.0	21	35.0	41	68.3	0	0.0	0	0.0	19	31.7
TOTAL (46)	690	461	66.8	98	14.2	17	2.5	114	16.5	488	70.7	91	13.2	4	0.6	107	15.5
Overall scores**		Total: 673; Range 41 to 46; Mean=44.7 (St. Dev 1.7)								Total: 686; Range 44 to 46; Mean 45.4 (St. Dev 0.8)							
Statistical testing**		Mann Whitney U= 94.500, p=0.407															

**'Total points' assumes one potential point for each subsection x 15 observed consultations in each group*

***Not observed scored '0'; observed, not applicable & implied scored '1' to calculate mean scores out of a top score of 46. Statistical testing compared mean scores of INPs with PGD users. INP = independent nurse prescriber, PGD = patient group direction.*

The few competencies that nurses did not achieve (n=20/1,380, 1.4%) are presented in Table 5-50, alongside the researcher's rationale for this judgement. Competencies "5.3: Guides patients/ carers on how to identify reliable sources of information about their medicines and treatments" and "5.4: Ensures that the patient/ carer knows what to do if there are any concerns about the management of their condition…" were the two least frequently observed.

Patient public involvement concerns

The PPI section of the framework identified that patients were most concerned about the effects of taking medications and the potential of side effects. There were five related RPS (2016) competencies, as presented in Table 5-51. Nurses predominantly addressed these concerns across all five competencies, with no differences between INPs and PGD users' practice (92.0% vs. 97.4%, respectively; $\chi^2 = 2.113$, df= 1, p= 0.146).

Table 5-50 Researcher's rationale for scoring 'not observed' in prescribing framework competencies

Competency	Rationale for scoring competency 'not observed'	INP or PGD	Incidences (n=20)
1.7 Reviews adherence to and effectiveness of current medicines.	Did not undertake compliance for Trichomoniasis	INP	1
2.6 Takes into account any relevant patient factors (e.g. ability to swallow, religion) and the potential impact on route of administration and formulation of medicines.	Patient reported difficulty swallowing tablets, suspension not offered; patient chewed the tablets. (No religion-specific aspects were identified during observations)	INP	1
4.2 Understands the potential for adverse effects and takes steps to avoid/minimise, recognise and manage them.	Does not provide information on potential adverse effects, and what to do if there is an issue. Does mention stomach cramps may be a side effect	INP	1
4.9 Electronically generates or writes legible unambiguous and complete prescriptions which meet legal requirements.	Written "COC" as prescription instead of full drug name/ prescription	INP	1
4.10 Effectively uses the systems necessary to prescribe medicines (e.g. medicine charts, electronic prescribing, decision support).		INP	1
4.12 Makes accurate legible and contemporaneous records and clinical notes of prescribing decisions.		INP	1
4.12 Makes accurate legible and contemporaneous records and clinical notes of prescribing decisions.	Did not write in clinical notes the rationale for providing thrush treatment and there was no indication from the notes it was required	INP	1
4.13 Communicates information about medicines and what they are being used for when sharing or transferring prescribing responsibilities/ information.		INP	1
5.3 Guides patients/carers on how to identify reliable sources of information about their medicines and treatments.	No clear indication information leaflet on condition or treatment given	INP	5
		PGD	2
5.4 Ensures that the patient/carer knows what to do if there are any concerns about the management of their condition, if the condition deteriorates or if there is no improvement in a specific time frame.	Follow-up booked, but did not discuss what to do if concerns in the meantime	INP	3
		PGD	2

INP= Independent nurse prescribing, PGD = patient group directions, COC = combined oral contraception

Table 5-51 Competencies based on patient and public involvement concerns

Competencies based on patient public involvement concerns	INP						PGD					
	Observed		Implied practice		Not observed		Observed		Implied practice		Not observed	
	n	%	n	%	n	%	n	%	n	%	n	%
3.3 Explains the rationale behind and the potential risks and benefits of management options in a way the patient/carer understands.	15	100	0	0.0	0	0.0	15	100	0	0.0	0	0.0
4.1 Prescribes a medicine only with adequate, up-to-date awareness of its actions, indications, dose, contraindications, interactions, cautions, and side effects.	6	40.0	9	60.0	0	0.0	7	46.7	8	53.3	0	0.0
4.2 Understands the potential for adverse effects and takes steps to avoid/minimise, recognise and manage them.	14	93.3	0	0.0	1	6.7	15	100	0	0.0	0	0.0
5.2 Gives the patient/carer clear, understandable and accessible information about their medicines (e.g. what it is for, how to use it, possible unwanted effects and how to report them, expected duration of treatment).	15	100	0	0.0	0	0.0	15	100	0	0.0	0	0.0
5.3 Guides patients/carers on how to identify reliable sources of information about their medicines and treatments.	10	66.7	0	0.0	5	33.3	13	86.7	0	0.0	2	13.3
Total	60	80.0	9	12.0	6	8.0	65	86.7	8	10.7	2	2.7

INP= Independent nurse prescribing, PGD = patient group directions

5.11.4 Autonomous practice

Both INPs and PGD users predominantly managed episodes of care autonomously (n=25, 83.3%), with no difference in autonomy between groups (Fishers Exact Test, p=1.000). Additional clinical/ medication support was required in five (16.7%) consultations, see Table 5-52.

Table 5-52 Autonomous practice

Autonomous practice	INP (n=15)		PGD (n=15)		Total (n=30)	
	n	%	n	%	n	%
Autonomous practice	13	86.7	12	80.0	25	83.3
Complex contraception referral	2	13.3	0.0	0.0	2	6.7
Medicine advice sought	0	0.0	1	6.7	1	3.3
Clinical advice sought & prescription obtained	0	0.0	1	6.7	1	3.3
Reduced duration of contraceptive pill supply due to PGD restrictions	0	0.0	1	6.7	1	3.3
Statistical testing (INP vs. PGDs)	Fishers Exact Test, p=1.000					

INP= Independent nurse prescribing, PGD = patient group directions

Section B:

This section utilises methods applied in previous aspects of the study by triangulating the clinical notes review and patient experience questionnaire with observed practice.

Clinical notes review:

5.11.5 Completeness of prescription documentation and method of medication delivery

Of the 47 drug items delivered during observations (INP=28; PGD=19), the medicine name was clearly documented in all but one record. Prescriptions' route, frequency and duration were less consistently recorded (see Table 5-53). INPs were statistically more likely to document the full 'prescription' compared to PGD users (INP=158, 94.0% vs. PGD=93, 81.6: χ^2= 10.791, df= 1, p= 0.001). INPs most often administered medication by injection (n=15, 53.6%), whereas PGD users (n=13, 68.4%) mostly supplied medication as 'to-take-out' oral treatment packs (n=13, 68.4%: Table 5-54).

Table 5-53 Quality of completed 'prescription' documentation

Completeness of 'prescription'*	Name		Dose		Route		Frequency		Duration		Signature		Summative score		Statistical testing (INP vs PGD)
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	
INP (n=28)	27	96.4	27	96.4	26	92.9	25	89.3	25	89.3	28	100	158 (/168)	94.0	χ^2 = 10.791, df = 1, p = 0.001
PGD (n=19)	19	100	14	73.7	13	68.4	14	73.7	16	84.2	17	89.5	93 (/114)	81.6	

**some patients were prescribed more than one drug; 47 drugs delivered over 30 consultations. INP= independent nurse prescribing, PGD=patient group directions, χ^2 = Chi-squared test*

Table 5-54 Method of delivering medication

Method of medication delivery	INP (n=28)		PGD (n=19)		Total (n=47)	
	n	%	n	%	n	%
'To take out' provided	9	32.1	13	68.4	22	46.8
Injection	15	53.6	3	15.8	18	38.3
Directly observed therapy	2	7.1	1	5.3	3	6.4
Pharmacy	1	3.6	1	5.3	2	4.3
Missing documentation in notes	1	3.6	1	5.3	2	4.3

INP= independent nurse prescribing, PGD=patient group directions

5.11.6 Safety in medication provision

Documentation of patients' past medical history, concurrent medication, allergies, and where applicable, pregnancy risk, were found in all consultations (Table 5-55). For two PGD cases these items were documented at a recent previous attendance; however, the nurse participants were observed asking these questions but it was not re-documented.

Table 5-55 Documentation of past medical history, concurrent medication, allergy and pregnancy risk

Accuracy of documented risk assessment prior to delivering medication (n=30)		**INP (n=15)**		**PGD (n=15)**	
		n	**%**	**n**	**%**
PMH documented	Documented	15	100	13	86.7
	Past documented	0	0	2	13.3
Concurrent medications	Documented	15	100	13	86.7
	Past documented	0	0	2	13.3
Allergies	Documented	15	100	13	86.7
	Past documented	0	0	2	13.3
Female patients only (n=19)		**INP (n=8)**		**PGD (n=11)**	
Pregnancy risk	Documented	8	100	11	100

INP= independent nurse prescribing, PGD=patient group directions

5.11.7 Medication appropriateness index

Twelve (40.0%) patients in the observation study had a pre-existing medical condition and/ or allergy, and 10 (33.3%) were taking concurrent medications (see Table 5-56). One patient was 9-11 weeks pregnant. The researcher considered these pre-existing issues throughout medication safety and appropriateness assessments.

Table 5-56 Number of patients with existing medical issues and/ or concurrent medication

Existing medical issues & concurrent medication	**INP (n=15)**				**PGD (n=15)**				**Total (n=30)**			
	No		**Yes**		**No**		**Yes**		**No**		**Yes**	
	n	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Pre-existing medical issue/ allergy*	10	66.7	5	33.3	8	53.3	7	46.7	18	60.0	12	40.0
Concurrent medication	11	73.3	4	26.7	9	60.0	6	40.0	20	66.7	10	33.3

** Allergies were considered alongside pre-existing medical conditions in 'medication-disease/ condition interaction' during medical appropriateness index assessments. INP= independent nurse prescribing, PGD=patient group directions*

Across the 47 individual drug items, the MAI demonstrated that both INPs and PGD users consistently provided appropriate medication (Table 5-57), in line with local and national treatment guidelines (BASHH, 2016; FSRH, 2016). Based on documentation alone, INPs provided two drugs that appeared not to be indicated for the conditions being managed (i.e. patient was prescribed clotrimazole cream and pessary when there was no apparent fungal infection). However, when triangulated with observational data the reason was clear i.e. the patient frequently suffered from antibiotic related thrush and was prescribed an antibiotic. Similarly, for PGD users, omissions on the documented 'prescriptions' led to poorer MAI scores for dosage (n=14, 73.7%) and directions (n=13, 68.4%). However, when triangulated with observational data there were no concerns related to medication appropriateness. Table 5-58 summarises the MAI scoring for INP and PGD based on documentation alone, then triangulated with observational data. There was comparable medication appropriateness scoring between both groups based on documentation alone ($t = -1.367$, $df = 32.7$, $p = 0.181$). Due to the MAI's weighted scoring system (which rates appropriateness 0-18, closer to 0 more appropriate, see page 146) had all aspects of the MAI been 'inappropriate' or 'not known' a total score of 846 (i.e. 47*18) could have been achieved. Both INP (score=19) and PGD users (score=31) scored very low, demonstrating a high level of appropriate medication delivery. Overall, based on documentation alone, 38 (80.9%) of medications scored '0', with a mean score of 1.0/18. Subsequent triangulation of observational data with documentation determined that all drugs were clinically indicated and likely to be therapeutically effective (n=47, 100%; MAI score 0/18 for INP and PGD users). Therefore, although documentation raised some concerns in relation to practice appropriateness, triangulation with the observations demonstrated that all observed consultations provided safe and appropriate medication delivery (n=30, 100%).

Table 5-57 Medication Appropriateness Index assessment (documentation & observations)

Medication Appropriateness Index	Source	INP (n=28)*								PGD (n=19)*			
		Appropriate		Intermediate		Inappropriate		Not known		Appropriate		Not known	
		n	%	n	%	n	%	n	%	n	%	n	%
Is there an indication for the medication?	Documentation	26	92.9	0	0	2	7.1	0	0	19	100	0	0
	Observation	28	100							19	100		
Is the medication effective for the condition?	Documentation	26	92.9	0	0	2	7.1	0	0	19	100	0	0
	Observation	28	100							19	100		
Is the dosage correct?	Documentation	27	96.4	0	0	0	0	1	3.6	14	73.7	5	26.3
	Observation	28	100							19	100		
Are the directions correct?	Documentation	25	89.3	0	0	0	0	3	10.7	13	68.4	6	31.6
	Observation	28	100							19	100		
Are the directions practical?	Documentation	27	96.4	0	0	0	0	1	3.6	13	68.4	6	31.6
	Observation	28	100							19	100		
Are there clinically significant medication interactions?	Documentation	26	92.9	2	7.1	0	0	0	0	19	100	0	0
	Observation	26	92.9	2	7.1	0	0	0	0	19	100		
Are there clinically significant medication-disease/ condition interactions	Documentation	28	100	0	0	0	0	0	0	19	100	0	0
	Observation	28	100							19	100		
Is there any unnecessary duplication with other medication(s)?	Documentation	26	92.9	0	0	2	7.1	0	0	19	100	0	0
	Observation	28	100							19	100		
Is the duration of therapy acceptable?	Documentation	25	89.3	2	7.1	0	0	1	3.6	16	84.2	3	15.8
	Observation	26	92.9	2	7.1	0	0	0	0	19	100		
Is this drug the least expensive alternative compared to others of equal utility?	Documentation	28	100	0	0	0	0	0	0	19	100	0	0
	Observation	28	100							19	100		

**number of individual medications delivered (not consultations). INP = independent nurse prescribing, PGD= patient group directions.*

Table 5-58 Medication Appropriateness Index weighted scoring results of documentation, then triangulated with observational data

Medication Appropriateness Index (MAI) Weighted scoring Documentation & triangulation with observational data^	INP (n=28)		PGD (n=19)		Total (n=47)	
	Documentation	Triangulation	Documentation	Triangulation	Documentation	Triangulation
Potential highest MAI weighted score (n x 18)	504		342		846	
Combined MAI weighted score	19	0	31	0	50	0
Mean MAI weighted score (out of 18)	0.7	0	1.6	0	1.0	0
Standard Deviation	2.0	0	2.5	0	2.3	0
Range of MAI weighted scores	0 to 7	0	0 to 6	0	0 to 7	0
Number scoring '0': most appropriate	25 (89.3%)	28 (100%)	13 (68.4%)	19 (100%)	38 (80.9%)	47 (100%)
Statistical testing (INP= 0.7 vs. PGD=1.6: Documentation only)	t = -1.367, df = 32.7, p= 0.181* mean difference -1.0 (95% CI: -2.4 to 0.5)					

**Range 0-18, the closer to 0 more appropriate **Levene's Test equal variances not assumed. INP = independent nurse prescribing, PGD = patient group directions, t= Independent Samples t Test, CI= confidence interval*

5.11.8 Patient experience feedback

Of the 30 observations, 27 patient experience questionnaires were distributed. A 96.3% (n=26: INP=14; PGD=12) response rate was achieved. From the 26 eligible responses, patients overwhelmingly reported a positive experience during their interactions with the nurse (see Table 5-59). INP and PGD nurses were reported as being: friendly and approachable (n=26, 100%); that they instilled confidence and trust for patients (n=25, 96.2%); explained the reasons for medication clearly (n=26, 100%); and were able to suitably answer questions (n=25, 96.2%). Where patients were aware the nurses provided medication autonomously, they all had confidence in the nurse doing so (n=14, 100%). While only 14 patients identified that nurses provided medication independently, in practice 25 (83.3%) of them actually received medication independently from the nurse.

Table 5-59 Patients' satisfaction with their consultation with nurses

Patients' satisfaction with nurses medication consultations		**Observation**					
		INP (n=14)		**PGD (n=12)**		**Total (n=26)**	
		n	**%**	**n**	**%**	**N**	**%**
1. Was the nurse you saw today friendly and approachable?	Definitely, yes	14	100	12	100	26	100
2. Did you have confidence & trust in the nurse you saw today?	Definitely, yes	14	100	11	91.7	25	96.2
	Missing answer	0	0.0	1	8.3	1	3.8
3. Did the nurse explain the reasons for the medicine in a way you could understand?	Completely, yes	14	100	12	100.0	26	100.0
4. If you had any questions to ask, were you satisfied with the answers?	Definitely, yes	14	100	11	91.7	25	96.2
	No opportunity	0	0.0	1	8.3	1	3.8
5A Did the nurse give you medication without speaking to a Dr?	Yes	8	57.1	6	50.0	14	53.8
	No	3	21.4	2	16.7	5	19.2
	Don't Know	3	21.4	0	0.0	3	11.5
	Missing answer	0	0.0	4	33.3	4	15.4
5B If **YES** did nurse have necessary skills	Number	8		6		14	
	Definitely, yes	8	100	6	100	14	100

INP =independent nurse prescribing, PGD= patient group directions

5.11.8.1 Satisfaction with Information about Medicines Scale (SIMS)

Patients predominantly reported that they were satisfied with the information they received about medicines (Table 5-60). The most common areas patients reported being less satisfied with information provision, related to medication potentially making them feel drowsy (positive score 17, negative score 7), whether they could drink alcohol (positive score 19, negative score 4) and the risks of getting side effects (positive score 19, negative score 4).

Table 5-60 Summary of satisfaction with information on medicines scale categories

SIMS category	INP (n=13)*		PGD (n=10)*		Total (n=23)*	
	n	%	n	%	n	%
Total potential score*	208	100	160	100	368	100
Too much (+0)	4	1.9	16	10.0	20	5.4
About right (+1)	154	74.0	135	84.4	289	78.5
Too little (+0)	5	2.4	4	2.5	9	2.4
No medication information received (+0)	15	7.2	2	1.3	17	4.6
Not applicable (+1)	29	13.9	3	1.9	32	8.7
Missed (+0)	1	0.5	0	0.0	1	0.3

**percentages based on the total potential scores, not the number of completed SIMS. SIMS: Satisfaction with Information about Medicines Scale, INP =independent nurse prescribing, PGD= patient group directions*

There was no difference in patients' satisfaction in relation to whether they were managed by INPs or PGD users (mean=13.1 vs. 10.7/16, respectively: Mann Whitney U=87.000, p=0.836: see Table 5-61). Patients reported marginally less satisfaction with information on the 'potential problems' with medications (mean=5.9/8) than with information on action and usage of medicines (mean=6.1/8).

Table 5-61 Summary of satisfaction with information on medicines scale scores

SIMS Scores	INP (n=14)	PGD (n=13)	Total (n=27)	Statistical testing** (INP vs. PGD)
SIMS potential score	224	208	432	Mann Whitney U= 87.000, p=0.836
SIMS score achieved	184	139	323	
SIMS mean score (/16)	13.1	10.7	12.0	
SIMS standard deviation	4.5	7.5	6.1	
AU total potential score	112	104	216	Mann Whitney U= 83.000, p=0.662
AU score achieved	95	70	165	
AU Mean score (/8)	6.8	5.4	6.1	
AU standard deviation	2.1	3.8	3.0	
PPM total potential score	112	104	216	Mann Whitney U= 82.000, p=0.630
PPM score achieved	89	69	158	
PPM Mean score (/8)	6.4	5.3	5.9	
PPM standard deviation	2.5	3.7	3.1	

**SIMS potential score is the highest score had every participant been completely satisfied with the medication information they received. **Statistical testing compared INP with PGD*
SIMS: Satisfaction with Information about Medicines Scale, AU: Action and usage of medicines score; PPM: Potential problems of medicines score. INP =independent nurse prescribing, PGD= patient group directions.

5.11.8.2 Content analysis of patients' handwritten comments

Nine patients (INP=5; PGD=4) left handwritten comments which covered several feedback content categories, as shown in Table 5-62. All comments were positive.

Table 5-62 Content analysis of patients' comments

Comment content category	INP	PGD	Total
Helpful	2	2	4
Informative/ knowledgeable	1	2	3
Lovely nurse	0	3	3
Approachable	2	0	2
Existing medication, no advice needed	1	0	1
Comfort/ put at ease	1	0	1
Would return to service	0	1	1
Reassuring	0	1	1

INP =independent nurse prescribing, PGD= patient group directions

5.12 Patient experience questionnaire: Task-specific methods

5.12.1 Purpose

Nurses providing medication independently is intended to improve patient care and experience; therefore, it is essential to obtain patients' feedback. The questionnaire (Appendix L) explored patients' satisfaction with their consultation and level of medicines' information received.

5.12.2 Method design

The patient experience questionnaire was a two-page document based on two validated research tools: Birmingham's sexual health service satisfaction questionnaire (Weston *et al.*, 2010) and the Satisfaction with Information about Medicines Scale (SIMS; Horne *et al.*, 2001). The first section enquired about patients' experience, confidence and opinion on nurses independently managing their care, using 'tick' boxes to highlight pre-determined responses. To facilitate a focussed line of enquiry only five questions from Weston *et al.*'s (2010) tool were used; those which were deemed by the researcher and supervisors to have face validity. While this may affect the overall validity, the questionnaire's phrasing was used to enhance the design of the tool used in this project. Moreover, Birmingham's questionnaire involved redundant enquires regarding all aspects of service interaction from initial contact through to leaving the clinic. The validity of this tool may, therefore, only be applicable to Birmingham's local service, as not all services will manage patient journeys in the same way (e.g. walk-in versus appointment). That being said, Weston et al.'s (2010) tool was specifically designed and tested to target sexual health patients, based on the speciality's unique governance requirements and patient demographics. Design and validation of the tool involved a systematic literature review, patient experience interviews and use of a Delphi technique to create the questionnaire's content. High levels of internal consistency were found (Cronbach's alpha 0.88) 'during your appointment' and 'overall impression'. Weston et al. (2010) concluded the questionnaire had good levels of content validity and was feasible to deliver in a sexual health setting. Patients reported they preferred completing the questionnaire in the clinic, rather than posting (Weston *et al.*, 2010). Therefore, patients within this study were requested to complete the questionnaire before leaving the clinic.

The second page of the patient questionnaire incorporated the SIMS validated tool which posed 17 questions regarding safe self-management of medication. The SIMS is based on research tool designed by Horne *et al.* (2001) to test how satisfied patients were in relation to medication information received. Their paper determined through using additional research tools (Medication Adherence Report Scale (MARS) and Beliefs about Medicines Questionnaire (BMQ)) in eight different clinical settings, that the SIMS had good levels of internal consistency (Cronbach's alpha coefficient 0.81-0.91), test-retest reliability (Pearson correlations 0.67-0.76, $p<0.05$) and ease of use. Moreover, a higher SIMS score related to higher levels of medication adherence (Horne *et al.*, 2001). The original scale had 17 questions; however, one question (question 8: How to use your medicine) was accidentally omitted during questionnaire printing. Therefore this study only included 16 questions. The SIMS has been evaluated for its acceptability (ease of use), internal consistency, test-retest reliability and criterion related validity. Therefore, this tool was used to determine sexual health patients' satisfaction with information and medication.

The draft questionnaire used for this project was sent to six patient representatives. They were informed of the questionnaire's context as receiving medication from a nurse in sexual health. Suggestions on formatting were provided, and one person, an experienced patient representative, reported that the participant information sheet was too long; consequently, this was shortened based on their suggestions.

5.12.3 Recruitment

Nurses undertaking the clinical diary were requested to distribute the patient experience questionnaires at the end of all consultations in which medicines had been delivered, regardless of whether this had been autonomously or otherwise. The recruitment phase was the same two-week period in which the nurses completed the diary. Questionnaires were distributed at the end of consultations and, to avoid coercion, deposited in a designated box placed in the reception. Return of completed questionnaire was regarded as implied consent.

5.12.4 Data collection

Patients who received medication from nurses completing the clinical diary were expected to receive a uniquely referenced questionnaire and a participant information sheet (English version Appendix M, Welsh version Appendix N) from the nurse. Questionnaire references were logged on the nurses' clinical diaries. Recording questionnaires in this way facilitated calculation of the response rate, and allowed further investigation should patients report inappropriate levels of advice; acknowledging not all SIMS's measurements are applicable to every medication. However, this did rely on nurses remembering to distribute questionnaires. Distributing the questionnaires in this way was deemed the most appropriate method; however, as Latter (2011) identified, self-selecting questionnaire distribution potentially creates a large bias. While the researcher acknowledged the distribution bias, it was the only feasible option based on governance, resources and clinical assessment. Given the confidential nature of sexual health, it was not possible for the researcher to retrospectively post questionnaires to eligible patients from the diaries' data. The number of sites (including satellite) and nurses participating, meant that the researcher was unable to personally distribute questionnaires. Moreover, not all patients fulfilled inclusion criteria (see 'Inclusion and exclusion criteria' on page 92). Nurses therefore identified whether or not patients fulfilled inclusion criteria. The diary did, however, record which patients did not receive a questionnaire which to some extent, addressed the bias issue.

The researcher collected the patient questionnaires in bulk when attending each site to collect the nurses' diaries. Data from the questionnaires were then transferred onto a specifically designed Microsoft Access® database. During the clinical notes review, the researcher also collected data on patients' diagnoses and medications where the questionnaire reference numbers could be traced back to specific patient episodes. All aspects of research governance and responsibility presented in Chapter 4 were also adhered to.

5.12.5 Analysis

Data related to Weston et al.'s (2010) patient experience questionnaire are presented as frequency distribution across the pre-determined responses. Due to the homogeneity in responses between both groups, and the obvious positive skew, statistical testing was not undertaken on consultation feedback. The SIMS is analysed on three different levels: firstly an overall picture providing general areas where medication information is lacking. The next section then provides a score on participants satisfaction levels, this is done be applying a score to each response: SIMS score '1' if 'about right' or 'not applicable'; '0' if 'too much', 'too little' or 'not received' as this suggests information wanting. Scores will range from 0-16, the higher the score, the higher the satisfaction. The full scale is then split into two further sub-categories: satisfaction relating to "Action and usage of medication" (questions 1-8); "Potential problems of medication" (questions 9-16). Cronbach's alpha coefficients for SIMS was tested on each of the SIMS scales and sub-scales to measure internal consistency/ reliability. The Cronbach's Alpha score is from 0 to 1, anything over 0.6 is considered to have a good level of internal consistency (Horne et al., 2001). The Independent Samples t Test was undertaken based on the mean SIMS scores between INPs and PGD users.

5.13 Patient experience questionnaire: Findings

5.13.1 Response rate

Of the 808 eligible patients who received medication from nurses during the clinical diary data collection, 393 (48.6%) were issued with a questionnaire; 380 were returned (96.7% response rate); consisting of INP=180 (47.4%), PGD=173 (45.5%), not known=7 (1.8%) and not completed=20 (1.1%). The overall usable response rate was 91.6%; however, this only represented 44.6% (360/808) of the overall eligible clinical diary patients. Table 5-63, presents the reasons questionnaires were not distributed, where this data was recorded.

Table 5-63 Distribution of patient questionnaires during clinical diary

Questionnaire eligibility	Comments and reasons for not distributing	Number	%
Eligible & given (n=393)	Traceable questionnaires	366	93.1
	Questionnaire reference missing/ illegible	27	6.9
Eligible, not given questionnaire (n=415)	No rationale	264	63.6
	Patient declined	29	7.0
	Forgot	26	6.3
	Patient in a rush	25	6.0
	Safeguarding/not appropriate	24	5.8
	Limited English	14	3.4
	AdHoc prescribing	13	3.1
	No questionnaire supply	11	2.7
	Referred to doctor	5	1.2
	Patient had eyesight issues	3	0.7
	Previous participation	1	0.2
NOT eligible & given	Not eligible for questionnaire but traceable	16	
Missing data on eligibility (so excluded)		29	

5.13.2 Patient's experience of the consultation

From the 360 eligible questionnaires returned, respondents overwhelmingly reported a positive patient experience during their interaction with nurses (see Table 5-64). INP and PGD nurses were reported as being: friendly and approachable (n=359, 99.7%); that they instilled confidence and trust for patients (n=357, 99.2%); explained the reasons for medication clearly (n=349, 96.9%); and were able to suitably answer questions (n=335, 93.1%).

Table 5-64 Patient's satisfaction with their consultations with nurses

Patient satisfaction with consultation		INP (n=180)		PGD (n=173)		Not known (n=7)		Total (n=360)	
		n	%	n	%	n	%	n	%
1. Was the nurse you saw today friendly and approachable?	Definitely, yes	179	99.4	172	99.4	6	85.7	357	99.2
	Some extent, yes	1	0.6	0	0.0	1	14.3	2	0.6
	Missing answer	0	0.0	1	0.6	0	0.0	1	0.3
2. Did you have confidence & trust in the nurse you saw today?	Definitely, yes	177	98.3	171	98.8	6	85.7	354	98.3
	Some extent, yes	1	0.6	1	0.6	1	14.3	3	0.8
	No	1	0.6	0	0.0	0	0.0	1	0.3
	Missing answer	1	0.6	1	0.6	0	0.0	2	0.6
3. Did the nurse explain the reasons for the medicine in a way you could understand?	Completely, yes	171	95.0	167	96.5	7	100.0	345	95.8
	Some extent, yes	1	0.6	3	1.7	0	0.0	4	1.1
	No	2	1.1	0	0.0	0	0.0	2	0.6
	Didn't need	5	2.8	2	1.2	0	0.0	7	1.9
	Missing answer	1	0.6	1	0.6	0	0.0	2	0.6
4. If you had any questions to ask, were you satisfied with the answers?	Definitely, yes	174	96.7	151	87.3	7	100.0	332	92.2
	Some extent, yes	1	0.6	2	1.2	0	0.0	3	0.8
	Did not have	4	2.2	18	10.4	0	0.0	22	6.1
	No opportunity	1	0.6	1	0.6	0	0.0	2	0.6
	Missing answer	0	0.0	1	0.6	0	0.0	1	0.3
5A Did the nurse give you medication without speaking to a doctor?	Yes	90	50.0	73	42.2	4	57.1	167	46.4
	No	36	20.0	38	22.0	2	28.6	76	21.1
	Don't Know	42	23.3	56	32.4	1	14.3	99	27.5
	Missing answer	12	6.7	6	3.5	0	0.0	18	5.0
5B* If 'YES' did the nurse have necessary skills?	Number:	90		73		4		167	
	Definitely, yes	89	98.9	68	93.2	4	100	161	96.4
	Some extent, yes	0	0.0	1	1.4	0	0	1	0.6
	No	1	1.1	0	0.0	0	0	1	0.6
	Missing answer	0	0.0	4	5.5	0	0	4	2.4

**Question 5A asked patients to only complete question 5B if they answered 'yes'. INP=Independent nurse prescribing, PGD= patient group direction*

When patients were asked “Did the nurse give you medication WITHOUT speaking to a doctor?”, only 90 (50%) managed by INPs and 73 (42.2%) managed by PGD users answered ‘yes’. In comparison, the analysis of patients’ clinical notes found 160 (89.1%) INPs and 127 (83.0%) PGD users’ medications were delivered to patient participants independently by the nurse. Nevertheless, 161 (96.4%) of the patients that were aware nurses delivered their medication independently ‘definitely’ had confidence in the nurse doing so, see Table 5-64.

5.13.3 Satisfaction with Information about Medicine Scale

Of the returned questionnaires, 348 (96.7%) fully or partially completed the SIMS section (INP=174, 96.7%; PGD=169, 97.7%; unknown=5, 71.4%). The summary of the SIMS results are shown in Table 5-65, detailed responses are presented in Appendix LL.

Table 5-65 Summary of satisfaction with information on medicines scale categories

SIMS category	INP (n=174)*		PGD (n=169)*		Not known (n=5)*		Total (n=348)*	
	n	%	n	%	n	%	n	%
Total potential score (n*16)	2784	100	2704	100	80	100	5568	100
Too much (+0)	223	8.0	187	6.9	0	0	410	7.4
About right (+1)	2062	74.1	1987	73.5	59	73.75	4108	73.8
Too little (+0)	57	2.0	56	2.1	5	6.25	118	2.1
None received (+0)	169	6.1	163	6.0	16	20	348	6.3
Not applicable (+1)	241	8.7	285	10.5	0	0	526	9.4
Missed (+0)	31	1.1	25	0.9	0	0	56	1.0

**percentages based on the total potential scores, not the number of completed SIMS. INP= independent nurse prescribing, PGDs= patient group directions, SIMS= Satisfaction with Information about Medicines Scale, (+0) = no score, (+1) = score of 1 per patients reporting about right or not applicable to the question. The higher the score the higher the satisfaction (maximum score =16 per full response)*

Nurses consistently scored very highly throughout, demonstrating high levels of patient satisfaction with medication information, as summarised in Table 5-65. About right (n=4108, 73.8%) and not applicable (n=526, 9.4%) were the highest scoring categories. From the ‘negative’ rated categories, nurses tended to provide ‘too much’ information (n=410, 7.4%), as opposed to not giving enough. Information components where patients were less satisfied related to: whether patients could drink alcohol while on treatment (positive score 251, negative score 95); whether the medication would make them feel drowsy (positive score 254, negative score 91); and what

they should do if they experienced side effects (positive scores 276, negative score 72). Nevertheless, these components still scored highly overall.

There was no difference in patients' satisfaction in relation to whether they were managed by INPs or PGD users (mean=13.3 vs. 13.5/16, respectively: t= -0.482, df= 341, p= 0.630: see Table 5-66). Patients reported marginally less satisfaction with information on the 'potential problems' with medications (mean=6.4/8) than with information on action and usage of medicines (mean=7.0/8), but there was no statistical differences between INPs and PGD users for these groups.

Table 5-66 Satisfaction with information on medicines scale scores

SIMS Scores	INP (n=174)	PGD (n=169)	Not known (n=5)	Total (n=348)	Statistical testing** (INP vs PGD)
SIMS potential score*	2784	2704	80	5568	Cronbach's α= 0.944 t = -0.482, df = 341, p=0.630 mean difference=-0.2 (95% CI: -1.1 to 0.6)
SIMS score achieved	2303	2272	59	4634	
SIMS mean score (/16)	13.3	13.5	11.8	13.4	
SIMS standard deviation	4.3	4.2	6.0	4.3	
AU total potential score	1392	1352	40	2784	Cronbach's α= 0.914 t = -0.960, df 341, p=0.338 mean difference=-0.2 (95% CI: -0.7 to 0.2)
AU score achieved	1196	1196	33	2425	
AU mean score (/8)	6.9	7.1	6.6	7.0	
AU standard deviation	2.2	2.0	2.2	2.1	
PPM total potential score	1392	1352	40	2784	Cronbach's α= 0.900 t = -0.022, df 341, p=0.983 mean difference=-0.0 (95% CI: -0.5 to 0.5)
PPM score achieved	1107	1076	26	2209	
PPM mean score (/8)	6.4	6.4	5.2	6.4	
PPM standard deviation	2.4	2.5	3.9	2.4	

**SIMS potential score is the highest score had every participant been completely satisfied with the medication information they received; SIMS: Satisfaction with Information about Medicines Scale, AU: Action and usage of medicines score; PPM: Potential problems of medicines score. INP =independent nurse prescribing, PGD= patient group directions, t= Independent Samples t Test, CI= confidence interval*

***Statistical testing compared INP with PGD, and excluded the 5 'not known' responses and those not completed*

5.13.4 Content analysis of patients' handwritten comments

One-hundred and two patients (INP=59; PGD=43) left additional comments at the end of their questionnaires, some covering multiple topics, as presented in Table 5-67. Every comment left was positive. Service delivery (n=44), professional knowledge (n=32), nurses' approachable nature (n=28) and their ability to put patients at ease (n=23) were valued by patient respondents.

Table 5-67 Content analysis of patients' comments

Comment	INP (n=59)	PGD (n=43)	Total (n=102)
Great or excellent service/ positive experience of service	30	14	44
Informative/ knowledgeable	20	12	32
Pleasant/ friendly/ approachable	15	13	28
Put at ease/ comfortable	11	12	23
Polite/ lovely/ kind/ nice	17	5	22
Very helpful	10	10	20
Thank you	6	4	10
Unrushed/ able to ask questions	4	6	10
Confidence in practice/ safe	4	5	9
Professional/ diplomatic	7	0	7
Perfect/ 10/10	4	1	5
Existing medication, no advice needed	3	2	5
Non-judgemental	3	1	4
Adequate/ OK/ satisfied	2	2	4
Great doctor or consultant	3	0	3
Answered all questions	3	0	3
Cared for	2	0	2

INP = independent nurse prescribing, PGD = patient group directions

5.14 Economic analysis: Task-specific methods

5.14.1 Introduction

Use of alternative service delivery models has the potential to affect resource requirements and costs, as well as the processes and outcomes of care. It may also impact on the job satisfaction and career progression opportunities of health professionals involved. This section explores the economic implications of use of INP vs. PGDs for the delivery of medications in sexual health clinics from the perspectives of the NHS (provider of care) and of individual nurses. It adopted a cost-consequences analysis (CCA) framework (Mauskoff et al., 1998) to compare INP and PGDs across various outcomes. In this way, this section has synthesised findings from the across different components of this study.

CCA was determined to be most suitable health economics evaluation methodology for this study because of the multiple influences, perspectives and potential effects associated with nurses' delivery of medication. Whilst cost-effectiveness and cost-utility analyses are the more frequently advocated approaches to economic evaluation (Drummond et al., 2015), these focus on a single clinical or health-related quality of life outcome which is less appropriate in the context of a service delivery intervention (Sutton et al., 2018) such as the comparison of INP and PGDs. CCA, on the other hand, supports the inclusion of non-health related factors, and processes of care. Outcomes of interest in the comparison of INP and PGDs included the appropriateness and safety of prescribing, impact on other health professionals in the team and the patient experience. CCA presents a costs balance sheet alongside the consequences, providing a broader and more comprehensive perspective of considerations and outcomes from an intervention, compared to other health economics methods. Data are presented as non-aggregated information rather than an overall cost-effectiveness or cost-utility ratio (Mauskopf et al., 1998). Hence, organisations and individuals can review specific aspects of the same dataset to determine whether the issues under consideration are likely to be economically beneficial from their perspective. Although a largely descriptive approach, CCA provides a framework for generating a clear summary of the differences between INP and PGDs for all stakeholders. In line with other approaches, drawbacks

of CCAs include their limited generalisability outside the organisation(s) or specialities being investigated, and vulnerability to bias when deciding which aspects to include.

The potential economic implications and consequences of INP vs. PGDs were identified at the outset to ensure relevant data were gathered throughout the study. Both INP and PGDs have benefits and barriers which ultimately affect resourcing, access of nurses to training, patient experience and service delivery. The main resource considerations from the perspective of the NHS and individual nurses are summarised in Table 5-68. These include, for the NHS, differences between INP and PGD in: set up/ staff training costs; medication prescribing; consultation duration; and impact on the workload of other professionals in the team. From the nurses' perspective, gaining an INP qualification, rather than using local PGD may involve: dedication of personal time to study and out-of-pocket expenses. Consequences arising in the context of these resource considerations were: patient experience of care (satisfaction with information received and the consultation) and career prospects and job satisfaction of nurses. Data captured for each item was embedded in other aspects of the study. Where resources were implicated, costs were subsequently attributed as appropriate, and where a statistical difference was demonstrated between INP and PGDs and compared between both groups. Further details of data capture, analysis and costing are presented in the methods section following the structure of Table 5-68.

Table 5-68 Components and data sources for cost-consequence analyses

Perspective		INP	PGD	Resource data source	Unit cost
NHS (cost implications)	Training & governance	HEI course	Not applicable	Staff interviews & questionnaires	Higher Education Institutes fees
		Senior staff supervision time			Apply unit costs of appropriate grade, according to time spent
		Study time & back fill			
		Not applicable	Time to write PGDs		
			Committee approval time		
			Time for local training of nurse		
	Clinic processes	Costs of medications prescribed		Review of clinic records	BNF
		Costs of wrong / under / over prescribing			
		Costs of inappropriate activity			
		Consultation duration		Nurse diaries	Apply unit costs of appropriate grade, according to time spent
		Impact on workload of other professionals		Nurse diaries, clinical records	
		Unplanned repeat consultation for index condition		Review of clinic records	
NHS (Patient outcomes)	Patient experience	Consultation experience		Patient questionnaire	Not quantified
		Satisfaction with information about medicines			
Private costs (nurse)	Training	Personal study time and loss of leisure		Staff interview & questionnaires	Unit costs of appropriate grade
		Out-of-pocket expenses, e.g. travel, materials			Expenditures reported
Private benefits (nurse)	Prospects	Promotion prospects, lifetime earnings			Estimated, discounted
		Subjective benefits, job satisfaction			Not quantified

INP= independent nurse prescriber, PGD= patient group direction, NHS= National Health Service, HEI= Higher Education Institute

5.14.2 Methods and costing

This section presents how resource data were sourced throughout the study and subsequently attributed within the CCA to identify differences in costs between INP vs. PGDs from the perspective of the NHS and individual nurses.

5.14.2.1 NHS perspective implications

Implications of INP vs. PGD from the perspective of the NHS are considered in two categories, 'Training & governance' and 'Clinic processes'. The investment in both INP and PGDs is intended to improve clinical processes (i.e. more efficient delivery of medications to patients and reducing demands on doctor time for prescribing). The key consequences thus have 'cost' as well as 'experience' implications, as under 'clinic processes' and 'patient experience'. See Figure 5-4.

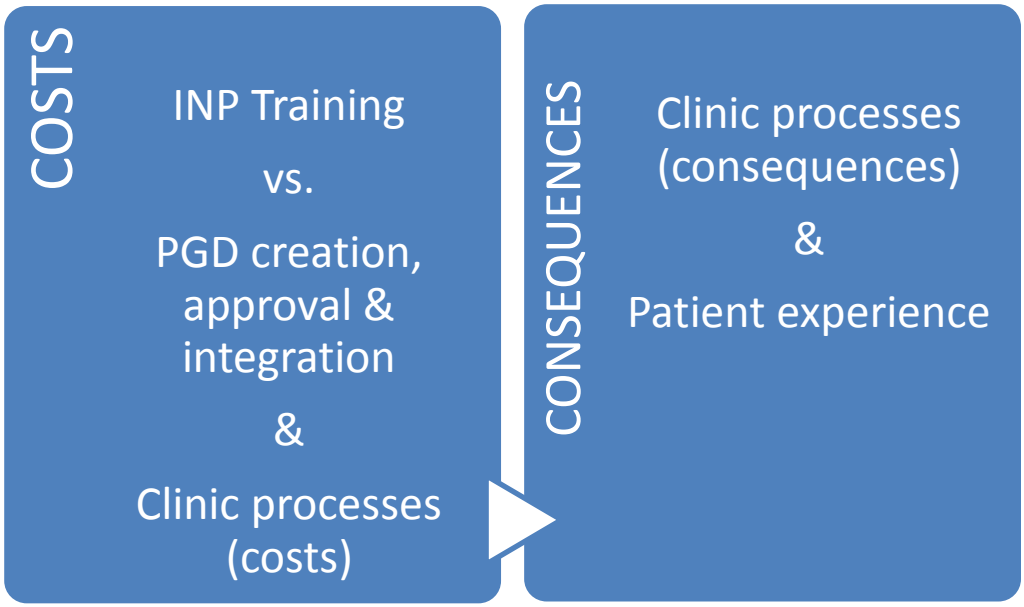


Figure 5-4 NHS costs and consequences analysis logic diagram

5.14.2.1.1 Training & governance

Training and governance for INPs and PGDs have different resource implications for the NHS. Data relating to this were gathered through staff interviews (Section 5.2 and 5.3), questionnaires (Section 5.4 and 5.5) and documentary reviews (Section 5.6 through to 5.9).

INP

Nurses wishing to embark on INP training needed to be sponsored by their local service. The decision to train was instigated by local teams or individual nurses. The NMC (2015) detailed that HEIs must provide INP training at Degree level or above over a minimum of 26 days, with a further 12 days (7.5 hours/day) of supervised clinical practice. The local NHS Trust provides a designated medical practitioner (DMP), who is expected to work with INP students in practice for the majority of these 12 days (which may have been alongside normal clinical activities) and provide support and guidance as required (NMC, 2015). Costs associated with INP training were applicable to individual nurses undertaking the training course. For some nurses who had previously used PGDs, the move to INP could involve incremental training costs.

Mean university fees were calculated based on the response to staff questionnaires that asked when and where nurses studied for INP. Each named university was contacted (or their website visited) to determine the current fees applicable during data collection (i.e. 2015/16). Every participant that answered this question was used to calculate the mean HEI costs. The DMP and clinical support hours were calculated where questionnaire respondents completed a time entry alongside the level of support they received (missing answers not included). This method will not be truly accurate as it was based on nurses' recall and self-reporting rather than accurate data recording. Moreover, it needs to be borne in mind that support provided by the DMP may have formed part of the DMP and/ or nurse's normal clinical responsibilities/ roles; therefore, the entire DMP/ nurses' time commitment may not have been additional work on top of normal duties. Staffing resources (dedicated DMP time) and study time were calculated based on hourly costing data from validated NHS unit costs for health and social care professionals, inclusive of all on-costs and overheads 2016 (Curtis & Burns, 2016). Whether nurses' roles were backfilled while undertaking training was not captured during data collection; however, this should be borne in mind as provision of study days meant clinical duties had to be covered by other staff members or clinics may have been cancelled.

PGDs

PGDs can be used by large numbers of nurses deemed locally competent. However, senior members of the NHS needed to invest considerable time and effort to obtain the required governance for PGD integration into practice. According to staff interviews and NICE (2013) this process involved creation, approval and implementation (see Figure 5-5). The time required to undertake this process will vary between authors, approval processes, governance restrictions, complexity of the drug / clinical management and availability of relevant stakeholders. During data collection the researcher's department required a new PGD for the contraceptive implant to be written, and nine further individual contraception PGDs to be updated following clinical guideline updates from FRSH (2016). The researcher was tasked with doing this which provided an opportunity to assess the resource implications of undertaking the PGD governance process. The researcher kept a log of the time taken to write and update the PGDs. The relevant stakeholders who edited/ authorised the PGDs (including clinical leads and Non-medical Prescribing Committee members) were also asked to log the time taken to review and edit the documents. Cost of staff times were attributed to nationally validated unit costs for the relevant health professionals 2016 (Curtis & Burns, 2016). With regards to updating the PGDs, it should be noted that nine PGDs were presented as a suite (i.e. single document with all PGDs contained within it) rather than individually. Subsequently time updating PGDs was divided by nine to obtain an estimate for updating an individual PGD; however, had they been individual documents the duration for updating is likely to have been longer.

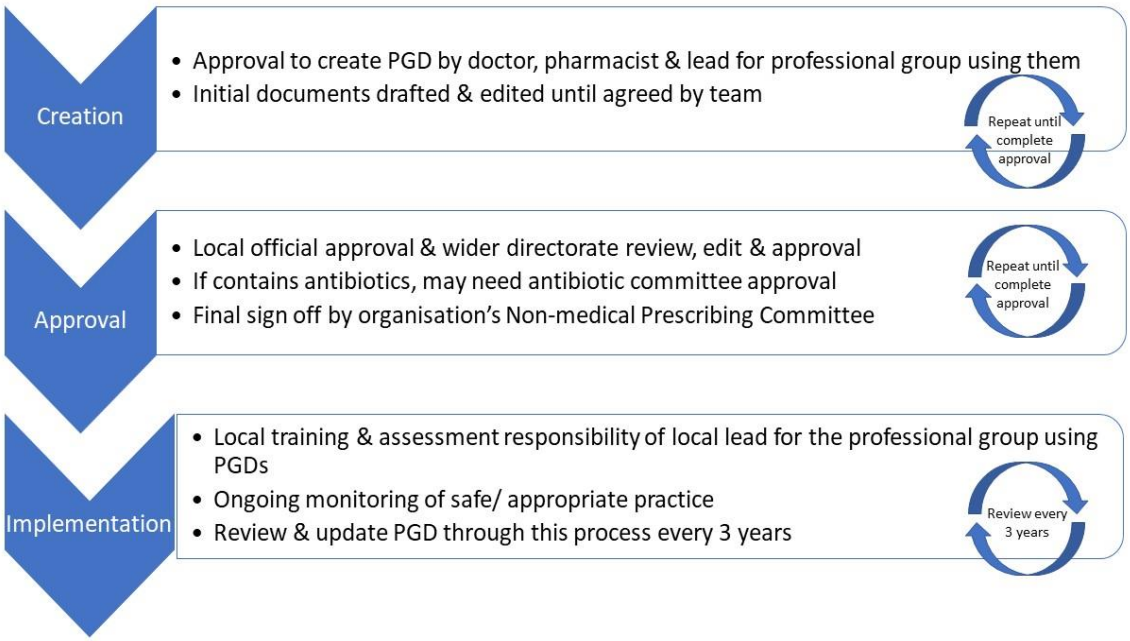


Figure 5-5 PGD approval process

5.14.2.1.2 Impact on clinic processes

The impact on clinical processes and patient experience are presented in Box 5.4

Box 5.4 Impact on clinical processes and patient experience:

Clinic processes included:

- Medications delivered
- Provision of safe medication delivery that was considered therapeutically effective for the conditions being managed (i.e. avoidance of wrong, under or over prescribing).
- Differences in consultation duration, after standardisation for differences in case load/ types of consultation.
- Differences in autonomous practice and the associated workload of other professionals.
    - Frequency of professional support required and reason (i.e. clinical management or medication advice)
    - Differences in impact on workload of other professionals in routine practice (including time that professional needed to spend).
- Differences in medical delivery appropriateness such that there are implications for costs of medications delivered or resource ramifications of inappropriate medications
- Differences in unplanned repeat consultations for the index condition.

Patient experience included:

- Ability to provide a high-quality service where patients have a positive experience following consultation by an INP or PGD user.
- Patients report receiving a suitable amount of information regarding the use of their medications.

Data to explore clinic processes were accessed through a variety of methods (see Table 5-68). Medications delivered were sourced through the clinical notes review. It was predicted that both INPs and PGD users would be working with locally procured medication formularies based on

local and national policies; consequently, they were likely to have limited ability to deliver unnecessarily expensive medication regimens. Costing medication choices were based on the BNF (2016) prices; even though local services may have secured better rates with manufacturers. The extent of wrong, under or over prescribing was established through the expert record review, as described in Section 5.9. Inappropriate medication activity was costed using the BNF (2016) as above. Wrong and over prescribing was taken as an indication of wastage and the cost of 'wasted' medication was estimated. For under-prescribing the medications that should have been prescribed were also estimated. The severity of prescribing errors, as presented in the clinical notes review, was also considered.

Consultation durations were recorded through observation (Section 5.11) and clinical diaries (Section 5.7). While observations were accurately timed, they were less likely to reflect actual practice as patients were purposively selected (as opposed to being normal practice) as delivery of medication was expected within the consultation. Also, only a small number of participants were involved. The clinical diary provided more quantitative data based on nurses' actual practice, although durations were based on estimates. Nevertheless, the diary was deemed likely to be more accurate for the purposes of costing consultation duration as it reflected actual practice. A mean consultation duration for INPs and PGD users was considered based on new, follow-up and overall consultations.

The impact of nurse delivery of medications on the workloads of other health professionals was also quantified (e.g. nurses obtaining prescriptions or clinical advice from doctors). This was based on data from the clinical diary (Section 5.7.4). Participants were prompted to record: the frequency of professional support required; who they sought support from; and how long that professional spent supporting them. The mean duration of support from different professionals was calculated and costed using validated unit costs for the relevant professional group 2016 (Curtis & Burns, 2016) to obtain an overall mean unit cost for professional support.

Unplanned re-consultation rates for the index condition were used as measure of the effectiveness of the initial treatment received. The number of unnecessary re-consultations due to sub-standard practice was calculated and compared between INPs and PGD users. Differences between re-attendance as consequence of test results, patients experiencing unexpected symptoms or adverse events (e.g. medication side effects) or relapses likely

attributable to patients' behaviour were counted but not analysed further for the purposes of cost as these were unlikely to have been influenced by whether the patient was manged by an INP or a PGD user.

5.14.2.2 NHS patient outcomes

The patient perspective was assessed in terms of their experience of their consultation and satisfaction with medicines information provided by INPs and PGD users. These data were collected from the patient experience questionnaires, see Section 5.13.

5.14.2.3 Nurses' private costs

Nurses undertaking medication delivery training may incur loss of leisure time to study, and some out-of-pocket expenses for travel and purchase of materials. There may also be employer expectations to expand their practice. As the NHS is primarily funding the course fess and study leave, it is expected that individual nurses invest personal commitment and time to achieve qualifications that improve their professional confidence, job satisfaction and career prospects. These components were included in narrative form in this CCA. See Figure 5-6.

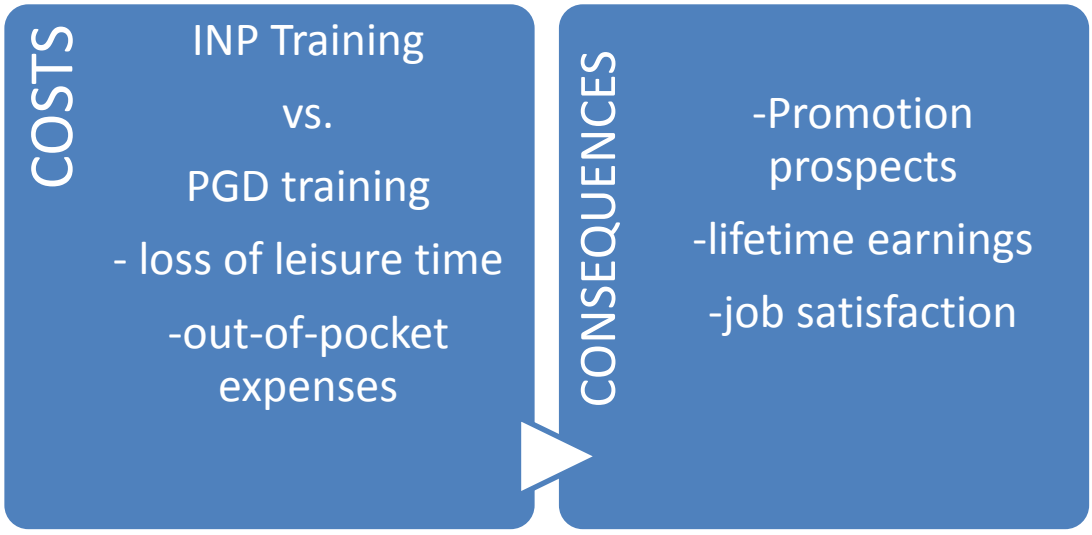


Figure 5-6 Nurses' private costs and consequences analysis logic diagram

Information on each of these elements was collected through the staff interviews (Section 5.3) and questionnaires (section 5.5). Loss of leisure time was calculated from the mean number of days respondents reported undertaking training in their personal time (mean did not include missing answers). The mid-point was taken where a range was provided. The cost was then calculated based on how much it would have cost the NHS to fund the nurse training in their personal time, using nationally validated unit costs 2016 (Curtis & Burns, 2016). Participants also reported a range of out-of-pocket expenses to complete training. Where values were reported by respondents, these were used to calculate the mean out-of-pocket expenses for INPs and PGD users which were then compared.

Nurses' private benefits

The potential financial returns to investment in training was estimated by comparing the promotion pathways for INP and PGD nurses based on respondents' current pay bands. Whilst a money value cannot be given to subjective benefits (e.g. job satisfaction) the opinions of INPs and PGD users from the staff questionnaires were considered in narrative form in this CCA.

Synthesis

The cost-consequences analysis (CCA) uses a balance sheet approach to present the range of costs and consequences, for the NHS, nurses and patients. Where possible costs and consequences are presented in quantitative form, otherwise a descriptive narrative is used. This provides a broader, more comprehensive perspective with inclusion of resource implications, costs, health and non-health related factors. The overriding purpose of the CCA was to compare INPs vs. PGDs as methods of medication delivery. The exploration of the costs and the returns aimed to determine the impact of the different medication delivery mechanisms on patient outcomes, clinic processes and costs to inform future service delivery decisions (Sutton et al., 2018). Only components with a statistical significance or clear resource differences (e.g. training resources and governance were clearly different for INP vs. PGDs) were included in the final CCA synthesis.

5.15 Economic analysis: Findings

5.15.1 NHS cost implications

This section presents the findings from the NHS resource and cost implications associated with INP and PGDs' 'training' and 'clinic processes'.

5.15.1.1 INP training resources

Higher Education Institution course fees

HEI fees were predominantly fully paid by employers or government health education grants (n=25/26, 96.2%), the remaining nurse partially self-funded. The staff questionnaires (Section 5.5.2) indicated that 26 INPs used ten different HEIs for prescriber training; 19 (73%) respondents reported that they trained between 1995 and 2015. Module fees were available from seven out the ten HEIs in 2016 (year of data collection) which identified a mean cost of £1,695.25; however, a wide range was noted (£900 to £3,555). Fees varied based on the number of academic credits offered (i.e. 15, 30, 40 or 60), level of study (i.e. Degree or Masters) and geographical location of the university. See Table 5-69.

Table 5-69 Higher education institution INP course fees

Measure	Cost during data collection
Year(s)	2016
Number of HEIs	7
Range (£)	£900 to £3,555
Mean (£)	£1,695.25
Standard deviation	779.10

INP= independent nurse prescribing; HEI= higher education institution

Supervision time with DMP and other senior staff

All 26 respondents to the staff questionnaire (Section 5.4) identified the grade of doctor who acted as their DMP (see Table 5-70). Based on the 23 (88.5%) respondents that reported duration of DMP supervised practice, it was determined that consultant doctors most frequently undertook the DMP role, providing a mean of 6.8 days (range 2 to 11). Consultants were the most expensive resource and, based on respondents in this study, cost the NHS a mean of £6,885.00 per student. However, five respondents reported that they spent the majority of clinical supervision with their consultant DMP (i.e. up to 12 days). Therefore, this potentially increased the DMP resource cost to £12,150 for each of these five students.

While clinical supervision was predominantly provided by DMPs, some respondents (n=14, 53.8%) reported additional support from other professional colleagues; 10 (71.4%) of whom provided the duration (see Table 5-70). Clinical supervision from nurse practitioners was the most frequently reported (n=4, 40.0%), aside from the DMP. Nurse practitioners were reported to have provided a mean of 1.9 days (range 1 to 3 days), costing £755.25. Based on the reported durations, inclusive of all professional colleagues that supported INP clinical supervision, a mean of 7.4 days (range 2 to 13.7) was provided, costing the NHS a weighted mean of £6,451.20 per INP student (range £1,282.50 to £11,137.50). It should, however, be borne in mind that the costs quoted are unlikely to be additional NHS expenditure as the majority of clinical support provided/ received was most likely associated with professionals' pre-existing clinical roles.

Table 5-70 Clinical supervision reported by INP respondents during training

Participant (n=26)	Designated Medical Practitioner (n=26) (7.5 hour days)				Other supervision (n=14 from the 26 respondents)(7.5 hour days)					Overall clinical supervision	Cost per nurse (£)^
	Consultant	Associate Specialist	Registrar	Total****	Associate Specialist	Registrar	Nurse Practitioner	Pharmacist	Total****		
1	5			5						5	£5,062.50
2	11			11						11	£11,137.50
3	8			8			✓			8	£8,100.00+
4	4.5			4.5				1.5	1.5	6	£5,253.75
5	4.5			4.5						4.5	£4,556.25
6	8			8						8	£8,100.00
7	8			8						8	£8,100.00
8	11			11		✓				11	£11,137.50+
9			8	8						8	£3,540.00
10			11	11						11	£4,867.50
11	11			11						11	£11,137.50
12	11			11			✓	✓		11	£11,137.50+
13	2			2	1.5				1.5	3.5	£3,465.00
14	2			2						2	£2,025.00
15			8	8						8	£3,540.00
16	8			8		2.7	3		5.7	13.7	£10,487.25
17			2	2			1		1	3	£1,282.50
18		5		5						5	£4,800.00
19	2			2						2	£2,025.00
20	11			11						11	£11,137.50
21	5			5		1	2	1	4	9	£6,765.00
22	5			5			1.5		1.5	6.5	£5,658.75

Participant (n=26)	Designated Medical Practitioner (n=26) (7.5 hour days)				Other supervision (n=14 from the 26 respondents)(7.5 hour days)					Overall clinical supervision	Cost per nurse (£)^
	Consultant	Associate Specialist	Registrar	Total****	Associate Specialist	Registrar	Nurse Practitioner	Pharmacist	Total****		
23	5			5						5	£5,062.50
24		✓		N/A						N/A	N/A
25	✓			N/A		✓	✓		N/A	N/A	N/A
26	✓			N/A						N/A	N/A
Measure	Amount of clinical supervision provided during INP training where a duration was provided (n=23/26, 88.5%)										
	Consultant	Associate Specialist	Registrar	Total****	Associate Specialist	Registrar	Nurse Practitioner	Pharmacist	Total****	Overall total****	Cost/nurse (£)^
Mean	6.8	5.0	7.3	6.8	1.5	1.9	1.9	1.3	2.5	7.4	£6,451.20
SD	3.3	0.0	3.8	3.3	0.0	1.2	0.9	0.4	1.9	3.3	3308.8
Range	2 to 11***	5	2 to 11***	2 to 11	1.5	1 to 2.7	1 to 3	1 to 1.5	1 to 5.7	1 to 13.7***	£1,282.50 to £11,137.50
Unit cost(/day)**	£1,012.50	£960.00	£442.50	£904.86 (221.84)	£960.00	£442.50	£397.50	£465.00	£486.18 (180.43)	£863.71 (251.00)	
Mean cost	£6,885.00	£4,800.00	£3,230.25	£6,153.05	£1,440.00	£840.75	£755.25	£604.50	£1,215.45	£6,391.45	

*✓= Support from professional group obtained, but no duration reported by participants. + = time on top of this entry, but no additional duration provided by respondent. N/A= unable to ascertain duration. *Missing durations entries (n=3/26) not included in this dataset. **Cost calculations: daily cost = [hourly cost] x7.5, mean costs= unit costs/day x total mean supervised days for each section. Hourly costs: Cost of specialist training support was obtained from 'Hospital-based health care staff' in Curtis & Burns (2016); page 191 for doctors: consultant doctor £135/hour; registrar £59/hour; associate specialist £128/hour. Page 188 for nurse practitioner band 7 nurse £53/hour; pharmacist Band 8 £62/hour (pharmacist was considered as Band 8 hospital nurse). ***where range given mid-point used: 0 to 3 was considered 2 days; 10 or over considered 11 days (full DMP supervision is 12 days; this range considered as 10-12). Overall supervision includes DMP time and additional supervision so overall range increases (however, these costs may be over-inflated as supervision was likely provided as part of clinicians' normal clinical roles) ****Total and total costs are weighted based on full data set (i.e. not a mean of means). SD= standard deviation. ^cost per nurse calculated from unit daily costs of DMP + other supervision.*

Study time & backfill

Twenty-four staff questionnaire respondents (seven 'Band 6', twelve 'Band 7' and five 'Band 8': section 5.5.2.1) identified a mean of 20.1 NHS provided study days to complete the INP training course, range 1 to 31 days. Based on all respondents' nursing bands, each study day cost the NHS a weighted mean of £394.50 per nurse/day. Considering all respondents' nursing bands, their associated daily rate (£330-£465.50) and the number of study days reported, it cost the NHS an additional weighted mean of £7,929.45 per nurse in study leave. Moreover, this weighted mean increased to £10,257 per nurse had the full 26 days HEI allocation been given (i.e. £394.50 x 26), which 12 (63.2%) respondents reported. See Table 5-71. Higher bands reported receiving more study days than more junior ones; however, it should be borne in mind respondents may not have been this band at the time they undertook the training. Moreover, these findings are specific to this cohort of respondents. Costs relevant to the range of study days provided per band are presented in Table 5-71.

Table 5-71 INP's professional study time National Health Service investment

Band	Responses (n)	Units (£)*	Study days				
			Measure	Range	Mean*	St. Dev	Total
6	7	£44/hr £330/day	n	3 to 26	16.7	9.4	117
			£	£990 to £8,580	£5,511.00	n/a	£38,610.00
7	12	£53/hr £397.50/ day	n	1 to 31	19.6	9.2	235
			£	£397.50 to £12,322.50	£7,791.00	n/a	£93,412.50
8	5	£62/hr £465.50/ day	n	26	26	0	130
			£	£12,103	£12,103.00	n/a	£60,515.00
All reported **	24	£394.50/ day	n	1 to 31	20.1	8.6	482
			£	£394.50 to £12,229.50	£7,929.45	n/a	£192,537.50

**Day cost= hourly costx7.5. Costs were based on from 'Hospital-based health care staff' in Curtis & Burns (2016); page 188 for Band 5 nurse £35/hour, Band 6 nurse £44/hour, Band 7 £53/hour, Band 8 nurse £62/hour **All means calculated from full relevant dataset (i.e. not based on mean of means). INP= independent nurse prescriber, SD= standard deviation*

Data on whether backfill was required to cover INPs while on study leave was not recorded; however, it is likely that at least some clinical services would require additional cover. It needs to be borne in mind that backfill could have been provided at lower or higher cost than the nurse on

study leave (e.g. junior nurse vs. doctor), but may not have been necessary for the entire period of absence.

5.15.1.2 PGD resources

This section sets out the resources with regards to the: time to write PGDs; committee time to approve PGDs; and training reported by nurses for them to use PGDs.

Time to write PGDs

Based on the approximate time in the researcher's log for writing, reviewing and obtaining departmental approval for a new contraceptive implant PGD, it took 7.8 hours. Using a similar process, the approximate duration to update a suite of nine PGDs averaged 1.7 hours per PGD. In each case this involved the researcher writing/ amending each PGD. In addition a consultant doctor and two band 8 nurses reviewed each document, provided feedback and approved each PGD from the department's perspective, as summarised in Table 5-72. Applying appropriate unit costs resulted in a total cost of £535.80 to write a PGD, ready for approval by the wider Directorate and Non-medical Prescribing Committee. Using a similar approach the cost to update each individual PGD was £106.50 (Table 5-72).

Table 5-72 Time to write PGDs based on staff resource log

Resource	Write PGD		Update PGD*	
	Hours**	Cost**	Hours**	Cost**
Primary PGD author (Band 8 nurse/ researcher)	5.1	£316.20	1.3	£80.60
Consultant doctor	0.8	£108.00	0.1	£13.50
Combined resource from department's Band 8 team (2x nurses)	1.8	£111.60	0.2	£12.40
Total	**7.8**	**£535.80**	**1.7**	**£106.50**

**The total time to update a suite of nine PGDs was divided by nine to give an approximate time to update each individual PGD. **Duration to write PGDs were approximations based on the researcher's log. Costs were based on from 'Hospital-based health care staff' in Curtis & Burns (2016); page 188 for Band 8 nurse £62/hour (and pharmacist was considered as Band 8 hospital nurse), page 191 for doctors £135/hour. PGD= patient group direction.*

Committee time to approve

Following local departmental approval, PGDs required Trust approval, initially from the Directorate leads, then the Non-medical Prescribing Committee. Durations in this section were based on individuals detailing how long it took them or estimations. It was determined to take approximately 30 minutes to review a new PGD and 15 minutes for an updated one (as the same staff had previously approved existing PGDs). Consequently, a new PGD took 5.0 hours for Directorate approval, and an updated one took 2.3 hours. The Directorate approval process involved a Band 8 pharmacist, Band 9 nurse and a consultant doctor. The Non-medical Prescribing Committee involved seven Band 8 nurses. The approval duration for each member is summarised in Table 5-73. Applying appropriate unit costs resulted in a total cost of £376.50 for Trust approval of a new PGD, and £169.20 to update a PGD.

It should be borne in mind that that these case studies of PGD development and updating maybe be under-estimates, as it was an experienced team who were also members of the Non-medical Prescribing Committee, so were aware of the pitfalls that stop PGDs being approved. Secondly, these PGDs only contained contraception. Had the PGDs included antibiotics it would have required additional committee approval (i.e. Antibiotic Resistance Committee). Therefore, the durations and costings for creating and approving PGDs cannot be deemed accurate for all approval processes.

Table 5-73 Committee time to approve PGDs

Resources	New PGD		Update PGD*	
	Hours**	Cost**	Hours**	Cost**
Lead pharmacist (Band 8)	0.5	£31.00	0.2	£12.40
Lead directorate nurse (Band 9)	0.5	£61.00	0.2	£24.40
Lead directorate clinician (consultant doctor)	0.5	£67.50	0.2	£27.00
Non-medical prescribing committee (x7 Band 8 nurses)	3.5	£217.00	1.7	£105.40
Total	**5.0**	**£376.50**	**2.3**	**£169.20**

**The total time to update a suite of nine PGDs was divided by nine to give an approximate time to update each individual PGD. **Duration to write PGDs were approximations based on the researcher's log or estimations. Costs were based on from 'Hospital-based health care staff' in Curtis & Burns (2016); page 188 for Band 8 nurse £62/hour (and pharmacist was considered as Band 8 hospital nurse) and Band 9 nurse £122/hour, page 191 for doctors £135/hour. PGD= patient group direction.*

Time for local training of nurse

Twenty-nine/35 (82.9%) PGD user respondents in the staff questionnaire (Section 5.4) reported a high level of variability with regards to how they were trained to become competent to use PGDs. Table 5-74 demonstrates the range of training methods reported. The most frequent method was classroom with a range of 1 to 30 students for a mean duration of 5.2 hours (however, this included two respondents reporting a full contraception HEI module where PGDs were only one section of the wider syllabus). One-to-one training was reported by 11 respondents, which was regarded as the most resource intensive method. However, self-directed learning was undertaken by 20 and e-learning by 10, which was cheaper, but it is not clear whether this was completed during work or personal time.

The high degree of variability in such a small sample led to skewed data on training duration. Based on all recorded responses (n=29), each PGD user spent a mean of 5.1 (SD 6.5) training hours (median and mode of 2.0 training hours). Whilst there is no requirement for the NHS to provide study days for PGD training, 30 respondents identified a mean of 0.9 NHS study days (6.4 study hours, range 0 to 85.2 hours); however, 16 (53.3%) were given no study time. The inclusion of the contraception university module skewed the mean study leave to be higher than mean training; however, the university module did facilitate supply of contraception through PGDs. Considering all respondents' nursing bands, their associated hourly rate (£35-£53/hr) and the number of study hours reported, it cost the NHS a mean of £332.25 per day/ nurse for PGD training, which pro-rata (6.4 hours*£44.30/hr) was £283.52 per nurse. Table 5-75 provides additional data on NHS provided study leave for PGD training. Similar to INPs, more senior PGD users were given a larger amount of study leave compared to more junior bands. It should, however, be borne in mind that these senior respondents were more likely to have been involved in the initial implementation of INP and PGDs into clinical practice when they were in more junior roles and when these extended clinical skills were in their infancy. Now INP and PGD governance has become fully integrated within services, and NHS resources have become more restricted, the amount of study leave offered to those new INP and PGDs appears to be reducing.

Table 5-74 Formal PGD training resources

Category of PGD training reported*	Responses from formal PGD teaching (n=29)		Number of PGD trainees in group					Training hours				
			Responses		Range (persons)	Mean	SD	Responses		Range (hrs)	Mean (hrs)	SD
	n	%	n	%				n	%			
Class teaching	23	79.3	14	60.9	1 to 30	10.9	7.8	14	60.9	0.5 to 30	5.2	8.6
Question & answer	20	69.0	7	35.0	1 to 15	9.1	4.7	5	25.0	0.5 to 8	2.7	3.0
Workshops	6	20.7	3	50.0	5 to 12.5	8.5	3.8	2	33.3	1 to 2	1.5	0.7
Self-directed learning	20	69.0						7	35.0	2.5 to 15	6.9	5.1
e-learning	10	34.5						4	40.0	1 to 5	2.1	1.9
One-to-one training	11	37.9						4	36.4	1 to 20	7.0	8.8

**Respondents may have had multiple methods of PGD training. Calculations based on completed entries in the staff questionnaires; mid-points used when a range given. Skewed results as a large amount of training involved lone training or classroom teaching with multiple students (i.e. e-learning 10 respondents reported lone personal training, whereas two respondents detailed classroom teaching with 30 students undertaking a contraception course which involved PGDs as one part of a larger syllabus). Interquartile range not used due to small sample size and need to capture all variations of PGD training. Trainers' costs not included or time taken to design training packages (as unable to calculate from data collected).*

Table 5-75 PGDs' professional study time (hours)

Band	Responses (n)	Units (£)*	Study hours (hours)						
			Measure	Range	Mean*	SD	Median	Mode	Total
5	4	£35/hr	n	0 to 15	4.3	7.2	1	0	17
			£	£0 to £525	£150.50	£252.00	£35.00	£0.00	£595.00
6	21	£44/hr	n	0 to 11.3	2.1	2.9	0	0	44.3
			£	£0 to £497.20	£92.40	£127.60	£0.00	£0.00	£1949.20
7	5	£53/hr	n	0 to 85.2	26	38.4	0	0	130.2
			£	£0 to £4,515.60	£1,378.00	£2,035.20	£0.00	£0.00	£6,900.60
All reported**	30	£44.30/hr	n	0 to 85.2	6.4	17.2	0	0	191.5
			£	£0 to £3,774.36	£283.52	£761.96	£0.00	£0.00	£8,483.45

** Costs were based on from 'Hospital-based health care staff' in Curtis & Burns (2016); page 188 for Band 5 nurse £35/hour, Band 6 nurse £44/hour, Band 7 £53/hour. This includes data from a university contraception training module that was not specific to PGDs, but did facilitate delivery of contraception through PGDs. **All results calculated and weighted from full relevant dataset (i.e. not based on mean of means). PGD= patient group direction, SD= standard deviation.*

5.15.1.3 Clinic processes

Costs of medications prescribed

The total cost for medication regimens delivered in the clinical notes review (see Section 5.9.6) across six months (01/07/2015 to 31/12/2015) was £20,053.67, based on the BNF (2016) prices. Some nurses managed HIV medication regimens. Given the high drug costs associated for managing HIV (£6,726.53), Table 5-76 presents the regimen costs both with and without HIV drugs. Without HIV medications the mean cost per patient was £9.82 (INP= £10.45; PGD= £9.29). However, these costs were not standardised for the potential differences between INPs and PGD users' caseloads.

Table 5-76 Medication regime costs

Total drug costs over 6 months	INP (n=620)	PGD (n=737)	Total (n=1357)
Total inc. HIV drugs (£)	£11,741.66	£8,312.01	£20,053.67
Mean cost per drug (£)	£18.94	£11.28	£14.78
HIV drug costs (£)	£5,264.79	£1,461.74	£6,726.53
Total exc. HIV drugs (£)	£6,476.87	£6,850.27	£13,327.14
Mean cost per drug (£)	£10.45	£9.29	£9.82

INP= independent nurse prescribers, PGD= patient group direction, n= number of individual drugs delivered

Costs of wrong/ over/ under prescribing

Overall, the expert clinical record review (Section 5.9.10) revealed that in the majority of instances INPs and PGD users provided appropriate medication regimens. However, there was a small number of instances where drugs were wrongly or over 'prescribed'. The cost of these medication regimens were estimated to give total wastage cost. The cost of the drugs that should have been prescribed were estimated for under-'prescribing', however, were not considered as a saving as patients may have needed to re-attend creating additional workload and poor patient experience. These sums are very small in comparison to overall drug expenditure and were similar between INPs and PGD users, therefore, the cost implications were minimal. See Table 5-77.

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Table 5-77 Costs of wrong/ under/ over prescribing

Costs of wrong/ under/ over prescribing	INP (n=620)			PGD (n=737)		
	n	%	Cost	n	%	Cost
Wrong prescribing (wasted)	12	1.9	£102.87	19	2.6	£103.72
Over-prescribing (wasted)	12	1.9	£77.41	16	2.2	£48.02
Under-prescribing	25	4.0	£144.03	19	2.6	£137.46

INP= independent nurse prescribers, PGD= patient group direction, n= number of individual drugs

Inappropriate medication delivery based on prescribing error severity (excluding wrong/ under/ over prescribing) found that any differences between INPs vs. PGDs were based on documentation quality as opposed to known harm to patients (Table 5-78). Therefore, there was limited benefit in comparing costs.

Table 5-78 Summary of inappropriate activity

Type of inappropriate medication delivery	INP (n=879)						PGD (n=965)					
	Minor error		Moderate		Severe error		Minor error		Moderate		Severe error	
	n	%	n	%	n	%	n	%	n	%	n	%
Considerations of drug interactions not documented	0	0.0	2	0.2	1	0.1	1	0.1	6	0.6	0	0.0
Inappropriate use of PGDs	0	0.0	0	0.0	0	0.0	34	3.5	29	3.0	0	0.0
Medication risk assessment	10	1.1	67	7.6	0	0.0	35	3.6	115	11.9	2	0.2
Prescription documentation omission	458	52.1	292	33.2	0	0.0	514	53.3	175	18.1	0	0.0
TOTAL	**489**	**55.6**	**388**	**44.1**	**2**	**0.2**	**602**	**62.4**	**361**	**37.4**	**2**	**0.2**

INP= independent nurse prescribing, PGD= patient group directions

Consultation duration

As presented in Section 5.7.3, despite an overall statistical difference being found in consultation duration between INPs vs. PGD users in the clinical diary (mean of 24.9 vs. 22.8 minutes, respectively, p=0.010), when adjusted for type of presentation (i.e. new vs. follow-up) there were no statistical differences found (i.e. new: 27.3 vs. 25.7 minutes, respectively, p=0.152). Consequently, cost analyses were not considered further.

Impact on workload of other professionals

Findings from the clinical diary (Section 5.7.4) demonstrated that when professional support was required, colleagues spent more time supporting INPs compared to PGD users (11.0 vs. 8.2 minutes, respectively); however, INPs required professional support less frequently than PGD users (12.9% vs. 25.6%, respectively, p<0.001). Both INPs and PGD users predominantly sought support from doctors (80.7% vs. 85.4%, respectively). Based on the weighted mean duration that the relevant professional groups provided support in the clinical diary, and cost data sourced from Curtis & Burns (2016), it was determined that it cost the NHS £10.41 per unit of professional support provided to INPs and £9.39 for PGD users. See Table 5-79.

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Table 5-79 Impact on workload for other professionals' support

Clinical diary: Impact on workload of other professionals	INP		PGD	
	n	%	n	%
Consultations where professional support sought (includes advice and prescriptions)	95/737	12.9	152/593	25.6
Statistical testing (diary)	χ^2= 35.281, df= 1, p<0.001			
Consultations with professional's time recorded	63/95	66.3	87/152	57.2
Range (minutes)	1 to 47		2 to 45	
Mean (SD) (minutes)	11.0 (11.7)		8.2 (6.9)	
Professional groups that provided support (where data recorded): Frequency of support	**INP (n=88)**		**PGD (n=164)**	
	n	**%**	**n**	**%**
Doctor	71	80.7	140	85.4
Nurse	5	5.7	16	9.8
Pharmacist	8	9.1	4	2.4
Health adviser	4	4.5	4	2.4
Estimated time & cost with each professional*	**Minutes**	**Cost (£)**	**Minutes**	**Cost (£)**
Doctor (Consultant: £135/hour; £2.25/minute)	369.6	£831.60	640.5	£1,441.13
Nurse (Band 7: £53/hour; £0.88/minute)	26.1	£22.97	73.5	£64.68
Pharmacist (Band 8A: £62/hour; £1.03/minute)	41.7	£42.95	18	£18.54
Health adviser (Band 7: £53/hour; £0.88/minute)	20.6	£18.13	18	£15.84
Total weighted cost for professional support	£915.65		£1,540.19	
Unit cost of professional support (based on mean)	£10.41		£9.39	

**Estimated time & cost calculated based on percentage of occasions a professional group's advice was sought from the 'total time for support' (e.g. Doctor's advice sought 80.7% of occasions; 80.7% of 458 minutes is 369.6minutes). Costs obtained from 'Hospital-based health care staff' in Curtis & Burns (2016); page 191 for doctors: consultant doctor £135/hour; page 188 for nurse practitioner (& health adviser) band 7 nurse £53/hour; pharmacist Band 8 £62/hour (pharmacist was considered as Band 8 hospital nurse).Unit cost for support calculated: Total weighted cost / number of occurrences where time data was recorded (e.g. INP: £915.65/88= £10.41). INP= independent nurse prescriber, PGD= patient group direction.*

Unplanned repeat consultation for index condition

Based on the clinical notes review (Section 5.9.13) 18.2% (n=306/1,682; INP= 145/743, 19.5%; PGD= 161/939, 17.1%) of patients returned in relation to their index condition, involving 400 reasons (INP=200; PGD= 200). The main reason was related to diagnostic laboratory tests being positive, which could not have been known at initial presentation. See Table 5-80. There were no indications that unplanned re-attendance was as a result of sub-standard care by either INPs or PGD users. Moreover, there were no statistical differences found between INPs vs. PGD users with regards to unplanned re-attendances, therefore, no costing analyses were made.

It was noted that patients being managed by an INP were statistically more likely not to attend planned follow-up appointments compared with PGD users (7.0% vs. 2.0%, respectively). However, this is unlikely to have been associated to whether they were managed by an INP or a

PGD user, but it does demonstrate potential difference in wastage of follow-up appointments. Based on previously presented weighted daily cost calculations for INPs (Table 5-71) and PGD users (Table 5-75) in this study, and follow-up consultations taking INPs a mean of 19.6 minutes and PGD users 20.0 minutes (Section 5.7.3) this resulted in a cost difference of £182.27 between the groups in potentially wasted staff time. This does not include on-costs, resources or recall attempts, nurses are likely to have undertaken other duties when patients failed to attend. See Table 5-80.

Table 5-80 Staffing resources for unexpected return for the index condition

Category for unexpected return	INP (n=200)		PGD (n=200)	
	n	%	n	%
Clinical/ diagnostic issue that was not known at initial visit*	99	49.5	101	50.5
Symptomatic or adverse issues that became apparent after initial visit *	59	29.5	56	28.0
Behavioural or processing issue which potentially could have been avoided (patients' behaviour was large component)*	28	14.0	39	19.5
Unexpected non-attendance to follow-up (did not attend)	14	7.0	4	2.0
Potentially wasted staffing costs (excludes resource, recall, on-costs)**	£241.47		£59.20	

**No statistical differences, costing analysis not undertaken. **statistical difference noted in did not attend (p=0.003, Section 5.9.13). Costs for wasted staff time calculated based on weighted daily cost for INP £394.50 (£52.60/hr; £0.88/minute) (Table 5-71) and PGD daily cost of £332.25 (£44.30/hr; £0.74/minute) (Table 5-75). Follow-up times based on mean of 19.6 minutes for INP, 20.0 minutes for PGD users from clinical diary (Section 5.7.3). INP= independent nurse prescriber, PGD= patient group direction.*

5.15.2 NHS patient outcomes

Patient experience: consultation experience

As presented throughout Section 5.13 there was no statistical difference in patients' experience of medication consultation or satisfaction with information about medicines between INPs vs. PGD users.

5.15.3 Nurses' private costs

Personal study time and loss of leisure

Twenty-one INP respondents to the staff questionnaire (Section 5.5) reported spending an additional mean of 26.3 'days' (i.e. 7.5 personal study hours per day), range 8 to 60 days, of their own personal time undertaking INP training. By comparison, 26 PGD users reported spending

1.6 ‘days’ of their own personal time undertaking training, but most respondents did not undertake any PGD training in their personal time (mode: 0 days). Undertaking studying in personal time impacts on leisure time, and could be regarded as saving to the NHS as this time is unlikely to be recompensed. It should, however, be borne in mind that the NHS is funding the course fees and supporting university study leave, as such some personal commitment is expected from individual nurses for continuing personal and professional development for their own academic and professional career development. Associated costs were based on previously presented weighted daily cost calculations for INPs (Table 5-71) and PGD users (Table 5-75) in this study. This equated to saving the NHS a mean of £10,375.35 per nurse had the NHS paid all for all INPs’ training requirements. PGD users undertaking training in their personal time saved the NHS £531.60 per nurse. See Table 5-81.

Table 5-81 Nurses' personal study time & loss of leisure

Loss of personal time (7.5-hour days)	**Self-study days**	
	INP (n=21)	**PGD (n=26)**
Range	8 to 60	0 to 10
Mean days (standard deviation)	26.3 (13.9)	1.6 (2.8)
Daily cost per nurse*	£394.50	£332.25
Mean personal study costs	£10,375.35	£531.60
Mode (days)	30	0
Mode personal study costs	£11,835.00	£0.00

**Costs for staff personal time calculated to determine how much it would cost the NHS to have paid for their time. These were based weighted daily cost for INP £394.50 (Table 5-71) and PGD daily cost of £332.25 (Table 5-75). INP= independent nurse prescribing, PGD= patient group direction*

Out-of-pocket expenses

Respondents in the staff questionnaire detailed additional out-of-pockets expenses they incurred to complete training. Predominantly across both INPs and PGD users there were no additional personal expenses reported. However, when expenses were incurred this was most frequently attributed to purchasing books (mean INP= £53.33; PGD= £5.00). Overall, INPs reported spending a mean of £32.02, compared to £1.49 by PGD users. These costs were not reimbursed by employers. See Table 5-82. However, one INP reported having travel, accommodation and childcare expenses as their university was situated in another city. Considering their expenses, this increased INPs’ mean out-of-pocket expenses to £40.19, but as this specific respondent had £200.00 travelling expenses reimbursed, the mean reimbursement for INPs was £8.33.

Table 5-82 Out-of-pocket expenses

Out-of-pocket expenses	INP (n=26)*					PGD (n=35)				
	Responses		Range	Mean (SD)	Mode (frequency)	Responses		Range	Mean (SD)	Mode (frequency)
	n	%				n	%			
Books	22	84.6	£0 to £250	£53.33 (60.50)	£0 (x6)	19	54.3	£0 to £40	£5.00 (11.36)	£0 (x16)
Additional travel	14	53.8	£0 to £150	£47.57 (47.55)	£0 (x3)	20	57.1	£0 to £3	£0.15 (0.67)	£0 (x19)
Stationary	17	65.4	£0 to £80	£19.26 (18.45)	£20 (x5)	21	60.0	£0 to £5	£0.71 (1.79)	£0 (x18)
Accommodation	14	53.8	£0	£0 (0)	£0 (x14)	18	51.4	£0	£0 (0)	£0 (x18)
OVERALL	67		£0 to £250	£32.02 (46.09)	£0 (x24)	78		£0 to £40	£1.49 (6.05)	£0 (x71)

**One INP respondent reported that their university was a considerable distance from their home, this required additional travel, accommodation and child care costs, some of which were refunded. As an outlier this was excluded from main analysis; however, their additional £400 expenses increased the overall mean cost of INP training from £32.02 to £40.19 (SD=61.70), but they got £200 travel reimbursed which created a mean of £8.33 reimbursement for all INPs. INP= independent nurse prescribing, PGD= patient group directions, SD= standard deviation*

5.15.4 Nurses' private benefits

Promotion prospects, lifetime earnings

The staff questionnaire (Section 5.5.2) highlighted that INPs (band 7= 13, 50.0%) were employed at higher bands compared to PGD users (band 6= 24, 68.6%). Based on respondents banding and unit costs for hospital nurses' salaries (Burns & Curtis, 2016) there was a difference of £5,519.42 in the annual salaries between INPs and PGD user respondents in this study (see Table 5-83). These differences have the potential to be compounded over the working lives of the respondents.

Table 5-83 Mean salary differences between INPs and PGD users

Mean salary difference*		**INP (n=26)**		**PGD (n=35)**	
		n	**%**	**n**	**%**
Band 5	£25,902	0	0.0	5	14.3
Band 6	£32,114	8	30.8	24	68.6
Band 7	£38,550	13	50.0	6	17.1
Band 8A	£45,204	5	19.2	0	0.0
Overall weighted mean salary (SD)		£37,849.31 (4,647.54)		£32,329.89 (3,596.76)	
Difference in mean salary		£5,519.42			

**Salaries calculated based on responses to current band in the staff questionnaire and the annual nursing salaries presented in 'Hospital-based health care staff' in Curtis & Burns (2016), page 188. INP= independent nurse prescribing, PGD= patient group directions, SD= standard deviation.*

Subjective benefits, job satisfaction

INPs and PGD users provided very similar responses to subjective benefits and job satisfaction related to their method of medication delivery. See Table 5-84.

Table 5-84 Costing subjective benefits, job satisfaction to INP and PGDs

Staff responses to subjective benefits of INP/ PGDs	INP				PGD			
	Positive		Neutral/ negative		Positive		Neutral/ negative	
	n	%	n	%	n	%	n	%
Impacted on respondents' clinical practice	72	92.3	3	3.8	97	92.4	5	4.8
Influenced patient experience	24	92.3	1	3.8	35	100	0	0.0
Affected respondents' personal confidence and satisfaction in practice	68	87.2	7	9.0	90	85.7	14	13.3
How training and continuing professional development prepared respondents	38	73.1	12	23.1	53	75.7	17	24.3
Whether respondents felt INP/PGDs were worthwhile interventions	46	88.5	4	7.7	64	91.4	6	8.6

INP= independent nurse prescribing, PGD= patient group directions

5.15.5 Synthesis

As the study progressed it became apparent that INPs and PGD users where highly comparable in a number of areas: safe and therapeutically appropriate delivery of medications; range of medications used, and diagnoses managed; unplanned repeat consultation for index condition; similar consultation lengths; professional experience; and provision of high quality care with high levels of patient satisfaction. Consequently, there would be minimal implications related to cost differences between these components. Therefore, the CCA balance sheet focussed specifically on aspects where statistical differences were found between INP vs. PGD users (see Table 5-85). The clear, but not unexpected, difference was related to the resource implications for training and governance. It should, however, be borne in mind that the significant costs for each individual INP trained are a single cost that can be discounted over several years following qualification. Whereas, the PGD costs are recurring for each individual PGD every three years, but PGDs have the benefit of being used by multiple staff members. Consequently, the more frequently INPs and PGD users use their medication delivery skills in clinical practice, the overall mean cost per patient will reduce.

When considering implementation of INP and PGDs, the CCA balance sheet can show the range of costs and consequences to different stakeholders. A worked example on the training implications is presented in Table 5-86. This demonstrates that although the mean cost to train an INP was £16,075.90, the actual cost could range from £900 to £27,808. The only fixed INP training cost was the university module. The subsequent allocation of DMPs' clinical supervision and number of study days provided are then decided locally between departmental stakeholders and individual nurses. However, as staff questionnaire respondents reported that the time spent with their DMPs was less than those expected of the NMC (2015), and nurses were likely to be autonomously managing patients during their DMP clinical supervision (as opposed to DMPs providing the entire supervision as dedicated training), these INP training costs may be overestimated. Whereas, in comparison to INP training, PGD creation, approval and training appeared to have relatively modest costs (Table 5-85). However, the PGD costs accumulated rapidly when applied to practical situations (Table 5-86). Across the five research sites a mean of 20.4 PGDs were in place (range 11 to 37, see Appendix GG) which were used by 13.4 nurses per site (range 8 to 18, see Section 4.8). Consequently, PGDs cost £17,998.92 to integrate, then

a further £3,799.17 for local internal training. Moreover, a three yearly recurring cost of £5,624.28 was required to maintain PGDs' governance. A further consideration with PGDs relates to the number of different drugs PGD users delivered in the clinical notes review (n=51). Creating a PGD for every drug required would increase PGD creation and approval costs to £44,997.30, with a three-yearly recurring cost of £14,060.70.

From the individual nurses' perspective, the primary difference between INP vs. PGDs was INPs undertook a significant amount of study in their personal time, which was not reported to the same level by PGD users. However, INPs were found to work at higher salary bands compared to PGD users but this cannot be solely attributed to being able to prescribe. Nevertheless, individual nurses can consider whether their personal time investment in continuing personal and professional development is worthwhile to further develop their career prospects.

Table 5-85 Cost consequence analysis balance sheet

Perspective		Cost/ consequence	INP cost	PGD cost	Difference	Comments/ unit measured
NHS (cost implications)	Training & governance	Higher Education Institute course (per nurse)	£1,695.25	£0.00	£1,695.25	Required for each individual INP student
		Senior staff supervision time (per nurse)	£6,451.20	£0.00	£6,451.20	If part of routine clinical duties costs may be significantly less than what are cited
		NHS study leave (per nurse)	£7,929.45	£283.52	£7,645.93	Not including backfill. Staff study leave may differ depending on amount locally allocated.
		Write each individual PGD	£0.00	£535.80	£535.80	Required for each PGD initially, but supports multiple staff to deliver medications.
		Update each individual PGD	£0.00	£106.50	£106.50	Each individual PGD is reviewed and updated on a 3 yearly cycle. Benefits multiple staff to deliver medications.
		Committee approval time for each new individual PGD	£0.00	£346.50	£346.50	Required for each PGD initially, but supports multiple staff to deliver medications.
		Committee approval time for updating each individual PGD	£0.00	£169.20	£169.20	Each individual PGD is reviewed and updated on a 3 yearly cycle. Benefits multiple staff to deliver medications.
	Clinic processes	Costs of medications prescribed/ patient	N/A	N/A	N/A	No statistical difference in therapeutically appropriate medication
		Costs of wrong / under / over prescribing	N/A	N/A	N/A	No statistical difference
		Costs of inappropriate activity	N/A	N/A	N/A	No statistical difference
		Consultation duration	N/A	N/A	N/A	No statistical difference
		Impact on workload of other professionals	£10.41	£9.39	£1.02	Unit cost of professional colleague per episode of support
		Unplanned repeat consultation for index condition	N/A	N/A	N/A	No statistical difference
		Unexpected non-attendance to follow-up	N/A	N/A	N/A	Difference not likely to be attributed to whether patients were managed by INP vs. PGD
NHS (Patient outcomes)	Patient experience	Consultation experience	N/A	N/A	N/A	No statistical difference
		Satisfaction with information about medicines	N/A	N/A	N/A	No statistical difference
Private costs (nurse)	Training	Personal study time and loss of leisure	£10,375.35	£531.60	£9,843.75	Mean weighted cost of staff time had they been paid for studying in their own time per nurse (i.e. potential saving to the NHS).
		Out-of-pocket expenses, e.g. travel, materials	£32.02	£1.49	£30.53	Mean cost per nurse

Perspective		Cost/ consequence	INP cost	PGD cost	Difference	Comments/ unit measured
Private benefits (nurse)	Prospects	Promotion prospects, lifetime earnings	£37,849.31	£32,329.89	£5,519.42	Salary difference/ year based on weighted bands and NHS salary costs from Curtis & Burns (2016); i.e. not the salary actually received by nurses. This difference cannot be solely attributed nurses being able to prescribe or use PGDs
		Subjective benefits, job satisfaction	N/A	N/A	N/A	No statistical difference

INP= independent nurse prescribing, PGD= patient group directions; NHS= National Health Service, N/A= not applicable

Table 5-86 Application of costs and consequences analysis balance sheet to compare training and governance

INP/ PGD	Resource	Requirement	Mean	Range	Total mean cost	Total cost range
INP	University fees	Mandatory university module	£1,695.25	£900 to £3,555	£16,075.90 (per nurse)	£900 to £27,808^ (per nurse)
	NHS study days	Locally determined (0-26 days)	£6,451.20	£0 to £12,103		
	Clinical supervision	Locally determined (12 clinically supervised days expected)*	£7,929.45	£0 to £12,150		
PGD	Write & approve a PGD**	Number locally determined	n=20.4	n=11 to 37	£17,998.92 (per site)	£9,705.30 to £32,645.10 (per site)
	Update a PGD***				£5,624.28 (per site)	£2,834.70 to £9,534.90 (per site)
	Local training****	Local training required, can be one-to-one or large groups	n=13.4	n=8 to 18	£3,799.17 (per site)	£2,268.16 to £5,103.36 (per site)

**12 clinical days expected, but this can be alongside normal clinical duties, as well as one-to-one additional training/ supervision. **For unit costs see Table 5-85: writing a PGD and committee approval time unit cost: £882.30 (£535.80 + £346.50). ***updating a PGD and committee approval time unit cost: £257.70 (£106.50 + 169.20), required every three years. ****unit cost of PGD training £283.52 per nurse, number of PGD nurses at all sites=67. ^£27,808 total cost is based on a Band 8 nurse undertaking the most expensive university course, receiving 26 study days & 12 additionally resourced consultant doctor designated medical practitioner clinical supervision days. INP= independent nurse prescribing, PGD= patient group direction*

CHAPTER 6: **Discussion**

6.1 Introduction

This chapter presents the overall contribution to knowledge, before discussing the study's findings under each of the research objectives. Each objective is subcategorised, as presented in Box 6.1. Table 4.1 on page 85 presents an overview of the data used to address each objective. Each category is then discussed individually. The study's limitations, practice implications are then discussed before concluding with recommendations for future research, and the overall conclusion on how INP and PGDs compare in sexual health.

Box 6.1 Study objectives & categories

1. Determine the extent to which nurses' professional experience and scope of practice affect prescribing practice or PGD use
    - Professional experience of those delivering medication
    - INPs & PGD users' scope of practice

2. Explore INP practice and the use of PGDs by nurses working in sexual health services; investigating frequency, range, appropriateness, safety and outcomes of medicines delivery.
    - Frequency of medication delivery
    - Range of medication
    - Appropriateness of medication delivery
    - Safety of medication delivery
    - Outcomes of medication delivery

3. To assess whether and how local application of INP and/ or PGD has benefited patients, health professionals and the NHS, with reference to quality of care, appropriate management of genitourinary and reproductive healthcare, and value for money
    - Benefits to patients
    - Benefits to health professionals
    - Benefits to the NHS
    - Quality of patient care
    - Appropriate management of genitourinary & reproductive care
    - Value for money

6.2 Contribution to knowledge

This study has further contributed to the existing knowledge base through a robust exploration of INP and PGD medication delivery with regards to clinical application, patient experience and costs. This is the first multi-site study known to have compared INP with PGDs, and the most detailed to investigate advanced nursing practice within sexual health. The use of mixed methods has triangulated findings from multiple perspectives creating a robust and thorough research design. Although restricted to sexual health, it is expected these findings are generalisable to other services where patients present for episodic healthcare, and in which nurses utilise INP and/ or PGDs.

Due to the robust nature of this study's design, use of validated research tools, and comparability of research methods to existing large scale prescribing studies (Dornan et al., 2009; Avery et al., 2012), it has been demonstrated that sexual health nurses are similar to other non-medical prescribers and doctors with regards to medication safety and error rates/ types. Moreover, this study has given confidence that nurses predominantly practice safely within their scope of practice, and appropriately seek support from the multi-disciplinary team when required. However, the findings also highlighted that PGD users sometimes exceeded their governance and legislation restrictions, albeit clinically appropriately. Nevertheless, patients were equally satisfied, and had confidence in both INPs and PGD users, and both groups provided appropriate levels of medication information.

An unexpected finding was the extent to which PGDs users were similar to INPs in managing sexual health conditions and provision of contraception. PGD users were highly comparable to INPs in terms of professional demographics, the type of sexual health conditions they were involved in managing and the range of medications they required access to; however, PGD users needed professional support from colleagues more frequently than INPs. Nevertheless, PGD users often performed better than INPs, with regards to completeness of documentation and medication errors, despite significant differences in medication training and assessment. A further outcome related to the variability in the number of PGDs, how they were integrated and provision of staff training across the five sites, which suggests further variability also exists across other organisations. However, the flexibility, ability of practitioners to practice autonomously, and the

university-based education associated with INP meant NHS managers overall were more confident and supportive of INP as compared to PGDs. However, there were also locally imposed restrictions that prevented some nurses becoming INP (i.e. based on their banding or confidence that PGDs suitably covered nurses' scope of practice). Nevertheless, both medication delivery methods were clearly shown to have extensive benefits in sexual health, despite resource and governance barriers.

Throughout the discussion, findings from this study are compared with existing literature. Although these comparisons are made, this project was the first known to explore INP application within clinical services to such depth, incorporating multiple lines of investigation, a costs assessment and validated research tools within a single study. Through triangulation, the strengths and weaknesses of the various research methods were highlighted, and demonstrated how findings and conclusions differed, based on how data were collected. Moreover, the geographical spread of participants and research sites across England, Scotland and Wales, provide an additional perspective on existing literature. Recent evidence specifically exploring PGD use in any clinical setting, and the current advanced practice role within sexual health, is lacking; therefore, this research has contributed to the current knowledge base in these areas. Despite growth in nurses' independent delivery of medications, there is scarce evidence available that has addressed the costs and consequences of integrating these skills. This study contributes to our understanding in this area, however, further robust health economics research is required.

6.3 Objective 1

Determine the extent to which nurses' professional experience and scope of practice affect prescribing practice or PGD use.

This objective is addressed under two distinct categories:

- Professional experience of those delivering medication
- INPs & PGD users' scope of practice

6.3.1 Professional experience of those delivering medications

INPs and PGD users in this study were found to be comparable in relation to the number of years they had worked as registered nurses, and their professional experience in sexual health. In-line with the prescribing literature (Courtenay et al., 2007a; Courtenay et al. 2007c; Latter et al., 2007c; Sibley et al., 2011; Carey et al., 2014; Cashin et al., 2014; Courtenay et al., 2017a), respondents were primarily female and aged between 33-55years. Most INPs (62%) were trained to Master's level, which is consistent with the most recent INP studies (Wilkinson et al., 2013; Courtenay et al., 2017a) but higher than the Degree level previously reported (Courtenay et al., 2007a; Courtenay et al., 2007c; Latter et al., 2007c; Smith et al., 2014). By contrast, the majority of PGD users were at Diploma level. In-line with the literature (Baileff, 2007; Courtenay et al., 2007c; Pontin and Jones, 2007) high numbers of INPs in this study (85%) reported that they had used PGDs prior to undertaking their prescribing role. However, despite having the prerequisite requirements for prescribing training (i.e. 3 years qualified experience and degree level qualifications: NMC 2006), many PGD users (41%) reported that they did not intend to become a prescriber. Not wanting to prescribe and no need to prescribe were reasons given for this. Conversely, other PGD users were keen to prescribe but were unable to obtain support from their employers. Reasons given by INPs for undertaking prescribing training included the desire to enhance their clinical skills, improve satisfaction with their role, and enhance patients' experience. By contrast, PGD users were more frequently required to use PGDs because of employers' expectations for them to do so.

From an organisational perspective, independent delivery of medication was found to have shaped nurses' roles and facilitated autonomous practice and nurse-led clinics e.g. outreach services for vulnerable groups (e.g. prisoners) or specialist treatment clinics (e.g. management of genital warts). Consistent with the literature (Black and Dawood 2013), independent delivery of medications was reported to be fundamental to the sexual health nurses' role. However, most participants reported that to make INP a prerequisite for certain roles within sexual health nursing (e.g. 'Advanced Practitioner') would be detrimental to the roles of PGD users and to sexual health service delivery, i.e. many skilled and capable nurses, for whom PGDs are effective, would be excluded from the role. From the employers' perspective, it was evident from the findings, that there were clear reasons why INP was preferable over PGDs. Independent prescribing was reported to provide greater flexibility with regards to meeting the dynamic needs of patients, prescribing was reported to be easier to manage (i.e. there was no need for PGD governance), and INPs had more in-depth knowledge of the medications they delivered. These benefits were a positive consequence of policies that supported prescribing practice (Human Regulations, 2012; NMC, 2015); however, INP training required significant initial investment which was not as high as that required for integrating PGDs. By contrast, PGDs were reported by employers to be clinically restrictive, 'cumbersome' to manage, and training was unregulated and regarded as 'superficial' in comparison to prescribing training. That being said, one service restricted INP for use by senior grades only, while another preferred PGDs, and did not see how INP would benefit the service if the provision of specific medication was within nurses' scope of practice.

It was evident from the findings that nurses' banding (i.e. Registered Nurses are put into a 'band' with 5 = lower band; Band 8 or 9 = higher band, and a higher commensurate salary/ managerial responsibility/ clinical expertise) was indicative of their expected clinical skills. Band 5 was regarded by employers as those roles leading into autonomous practice including varying abilities to utilise PGDs. Although the expectations of band 6 nurses varied across sites, all band 6 nurses were able to use every locally available PGD. Most case sites (sites 2-5) regarded band 6 nurses as fully autonomous practitioners who could become INPs. The remaining site (site 1) restricted nurses' ability to become an INP to band 7 and higher. This banding segregation was also evident in the findings of the staff questionnaires, i.e. there were no band 5 INPs and most PGD users (69%) were band 6. In-line with other research (Courtenay et al., 2015; Courtenay et al., 2017a)

INPs were mostly banded higher than those who didn't prescribe. Similar banding variations have also been found across England's Mental Health organisations where INP training was reported to be primarily available for band 6 nurses (Dobel-ober and Brimblecombe, 2016), and concerns have been raised by some INPs that the prescribing skill will be expected of lower grades in the future to save money (Carey et al., 2014).

6.3.2 INPs and PGD users' scope of practice

The staff interviews highlighted that expanding nurses' ability to deliver medication facilitated the development of sexual health nurses' scope of practice, moving them from 'doctors' handmaidens' to autonomous practitioners. Although PGDs were positively regarded when first introduced in case study sites, their restrictive nature became increasingly apparent as nurses' scope of practice expanded to include prescribing. However, some restrictions were also reported with regards to prescribing. For example, some INPs were restricted by local formularies (i.e. lists of medicines to which all prescribers must adhere), whilst others had to create personal formulary portfolios (likened to writing personal PGDs) in which evidence had to be recorded (including drugs' indications, contraindications, regimens and side effects) for each drug they could prescribe. Consequently, some INPs reverted back to using PGDs where drugs were not included in their portfolios, thus losing the benefits of prescribing and the value of the investment in training INPs. However, a paper detailing the integration of a prescribing formulary within a mental health service identified that a local drug formulary supported particularly new prescribers and enhanced their confidence in taking on the prescribing role and improved communication with service users (Dobel-Ober et al., 2013). This, therefore, could indicate potential benefits for personal formularies for new INPs, although, as found in this study, these formularies can be overly restrictive for more experienced INPs.

The results differed somewhat between the two subgroups of nurses within sexual health (i.e. genitourinary care and reproductive health). INPs' scope of practice in genitourinary care was found to be overall more advanced than PGD users (i.e. INPs were trained to manage more clinically complex patient presentations). The ability to prescribe in genitourinary care clearly

supported advanced clinical practice, which had a positive impact on service delivery i.e. participants reported improved efficiency by reducing time spent obtaining prescriptions; helping services to run smoothly and managing more patients through nurse delivered clinics. This facilitated convenient patient access to medicines and information. However, a similar finding relating to advanced practice was not found between INPs and PGDs users in reproductive health (i.e. both groups mostly provided simple contraception). This is most likely because advanced practitioner roles in reproductive health requires further competency-based assessments through supervised practice, to achieve the Faculty of Sexual & Reproductive Health's 'Letter of Competence'. Moreover, three sites (sites 1, 2 and 3) had not yet fully integrated reproductive healthcare with genitourinary care. This restricted the level at which nurses could practice due to the sites' local governance processes which affected the availability of services locally.

Sexual health nurses reported that they felt confident delivering medications independently and this subsequently increased their job satisfaction. A similar increase in nurses' confidence in medication delivery has also been found in other clinical areas (Gumber and Gajebasia, 2012; Carey et al., 2014; Creedon et al., 2015). While most respondents reported that the prescribing programme adequately prepared them for their prescribing role, several respondents felt unprepared. The reasons for this were not explored. Commonly cited reasons include a lack of pharmacology knowledge, advanced clinical/ assessment skills and specific practice-area skills (Latter et al., 2007c). Furthermore, a small number of INPs and PGD users in this study felt unsupported with regards to continuing professional development (CPD) as they were unable to access training. This supports previous literature in which time to access CPD has been identified as a barrier to independent medication delivery (Creedon, 2010; Smith et al., 2014).

6.3.3 Objective 1 summary

Independent delivery of medications is fundamental to the role of sexual health nurses, and it was evident that both INPs and PGD users in this study were highly experienced professionals. INPs' desire to enhance their clinical skills, improve satisfaction with their role, and enhance patients' experience, acted as drivers to undertake prescribing training. By contrast, PGD users were

driven to use PGDs as a result of their employers' expectations for them to. Although many PGD users possessed the necessary knowledge and experience to become prescribers, they chose not to do so. Employers heavily influenced both INPs and PGD users' ability to deliver medication and scope of practice. This was often based on nursing 'bands'. Subsequently, scope of practice of INPs and PGD users varied not only between users, but also between organisations. Although the modern sexual health nursing role was consistently found to be reliant upon independent delivery of medicines, a need for CPD was identified by both INPs and PGD users.

6.4 Objective 2

Explore INP practice and the use of PGDs by nurses working in sexual health services; investigating frequency, range, appropriateness, safety and outcomes of medicines delivery.

This objective is addressed under five distinct categories:

- Frequency of medication delivery
- Range of medication
- Appropriateness of medication delivery
- Safety of medication delivery
- Outcomes of medication delivery

6.4.1 Frequency of medication delivery

The clinical notes review identified INPs and PGD users frequently delivered medications in sexual health (54% vs. 48% of care episodes, respectively). This is consistent with Black's (2012) findings from a single site sexual health service. Such frequent medication delivery reduces the overall cost-per-patient over time as the more often nurses deliver medications, the greater the

return from the initial investment in INP and PGD training and governance becomes. Moreover, findings from the clinical diary suggested nurses with greater confidence in their clinical practice delivered medications more frequently than the overall nursing team. Although it was evident from the clinical notes review that the frequency of medicines delivery between INPs and PGD users was statistically significantly different, both groups delivered medications to approximately every second patient. Given that 2.7million patients in England attend sexual health clinics each year (PHE 2017), this highlights the important role nurses play with regards to medicines delivery.

6.4.2 Range of medication

It was evident from the clinical notes, that both INPs and PGD users delivered a similar range of medications, totalling 66 different drugs (56 vs. 51, respectively). INPs were found to be able to deliver a flexible and extensive range of medications autonomously. However, the inflexible nature of PGDs meant that users frequently sought prescriptions from colleagues, the arduous and cumbersome nature of PGDs making it impossible to create individual PGDs for the extensive range of drugs and clinical presentations manged by sexual health nurses. Therefore, local managers need to weigh the resource implications of creating multiple PGDs for frequently used medications versus PGD users' need to obtain prescriptions from colleagues. Nevertheless, evidence from this study suggests that independent access to some medicines is better than no access at all, in line with previous research (Black and Dawood, 2013).

Bacterial infections were the conditions for which medicines were required most frequently, and unsurprisingly antibiotics were delivered most often across both groups. The most common drug delivered was azithromycin. This was delivered by both INPs and PGD users to treat chlamydia, the most common bacterial STI (PHE, 2017). This highlights that antibiotic stewardship is a key responsibility for those delivering medicines in sexual health. Documentary evidence and observation data demonstrated that sexual health nurses delivered antibiotics responsibly and in line with guidelines (BASHH, 2016). This aligns with research that has explored the prescription of antibiotics by nurse and pharmacist prescribers for patients with respiratory tract infections (Courtenay et al., 2017b).

6.4.3 Appropriateness of medication delivery

It was evident from the findings that sexual health INPs and PGD users delivered clinically appropriate medications. Although not specifically exploring sexual health, this is in-line with previous nurse prescribing research that has used the Medication Appropriateness Index (MAI: Latter et al., 2007b; Latter et al., 2012; Naughton et al., 2012). The low mean MAI weighted score (clinical notes= 0.9/18; observations= 1.0/18) established that INPs and PGDs users made highly comparable and appropriate medication choices, with many medications delivered with no inappropriate scores; i.e. clinical notes= 82%; observation documentation= 81%, which increased to 100% when triangulated with observed data. This is higher than MAI assessments reported previously (Latter et al., 2012).

From the MAI's ten points of enquiry, both INPs and PGD users scored most appropriately on the question relating to using most cost efficient medication regimens being delivered. This concurs with previous research (Latter et al., 2012) and is perhaps unsurprising given that sexual health nurses in this study worked with a range of detailed evidence-based guidelines (BASHH, 2016; FSRH, 2016) and locally procured formularies. INPs and PGDs users also scored very highly on the components 'indication for the medication', and 'medicines effectiveness for the condition' managed. This is in-line with work by Naughton et al. (2012), investigating nurse prescribing in multiple clinical specialities across eight hospitals. These researchers concluded that there were no clinical benefits for the medication if these components were not met. There was some variability between INPs and PGD users with regards to the areas with the most inappropriate MAI scores. For INPs these related to appropriateness of dose, correct medication directions and directions being practical, whereas, for PGD users this was related to drug-drug interactions, medical condition-drug interactions and correct medication directions. Similar inconsistencies amongst prescribers have been reported previously (Latter et al., 2007b; Latter et al., 2012; Naughton et al., 2012). It is important to note that the primary reason INPs and PGD users scored inappropriately on the MAI was because of omitted documentation, as opposed to inappropriate

practice. However, when this information was triangulated with observation and documentary evidence, every aspect of the MAI reached 100%. This demonstrates the importance of comprehensive documentation, and the limitations of using clinical records for assessing medication appropriateness.

Appropriate use of PGDs?

From a clinical governance perspective, INPs and PGDs users were comparable, and both groups appropriately delivered medications expected to be therapeutically beneficial. However, PGD users were more likely to practice outside of their restrictions (i.e. evident in 8% of medication deliveries). This has been reported previously (Williams and Knox, 2011; Black and Dawood, 2013). Interview data highlighted that in some instances, PGD users inadvertently overlooked exclusion criteria included in the direction. For example, some patients were appropriately supplied doxycycline for the management of proctitis or cervicitis; however, these conditions were either excluded (i.e. proctitis) or not listed in the inclusion criteria (i.e. cervicitis). This finding raises concerns over authorisation and training. It is important to ensure that PGD users are educated to ensure safe practice and are compliant with PGD governance. However, it is also important, given that medicines delivered outside of PGD restrictions were clinically appropriate, that PGDs also correctly reflect users' scope of practice. This became particularly apparent in site 1 when all symptomatic patients infected with gonorrhoea were unnecessarily excluded from being managed by PGD users. As PGD users had the clinical competence to manage gonorrhoea, there was no obvious requirement for patients to be managed by a prescriber. This specific PGD restriction was subsequently removed. Overall, despite some cases where the boundaries of PGDs were pushed, there were many more cases of appropriate, safe clinical practice by PGD users.

6.4.4 Safety of medication delivery

Patients' pre-existing risk factors

It was evident from the findings that both INPs and PGD users did not consistently document their medication safety assessments in terms of patients' pre-existing risk factors (i.e. medical history, concurrent medication, allergies, pregnancy risk). INPs were statistically more likely to fully document these factors compared to PGD users. Although not in sexual health, this lack of documentation has been highlighted previously in the general prescribing literature (Latter et al., 2007a; Carey et al., 2009; Williams and Know, 2011; Price et al., 2012; Black, 2012). However, observational data demonstrated that risk factors were always fully discussed during consultations.

Both INPs and PGD users managed similarly complex clinical presentations in terms of patients pre-existing medical conditions, allergies and/ or concurrent medication, which could have influenced medications' safety or effectiveness. Although the findings demonstrated potential drug-drug or drug-disease interactions, both INPs and PGD users predominantly provided medications safely; i.e. the medication benefits outweighed their risks. However, four cases of potentially unsafe drug-drug interactions were identified based on the patients' documented concurrent medications, and the new medications delivered by INPs and PGD users in this study; however, no patients were known to be harmed.

Completeness of the prescription

The most frequent medication errors made by both INPs and PGD users related to incomplete information on prescriptions. This concurs with findings by Avery et al. (2012) in research exploring medication errors by prescribers in general practice. Although both groups omitted information on drug dose, routes, administration frequencies and durations, PGD users provided significantly greater details than INPs. Nevertheless, findings in this study identified that both INPs and PGD users provided less complete 'prescriptions' than the findings reported in the general nurse prescribing literature (Baileff, 2007; Latter et al., 2007a; Carey et al., 2009; Drennan et al.,

2011) but this comparison may be influenced by varying authors definition of what constitutes a complete prescription. For example, this study considered that if the 'route of administration' was missing it constituted an error, whereas, other studies may not have counted this as an error if there was only one formulation of a drug.

Medication errors

The Medication Protection Society (2016) reported that medication errors were the second most common cause for healthcare litigation; citing contraindicated drugs (most commonly antibiotics), providing the wrong drug or selecting an incorrect dose as most frequent. Dose related errors have also been reported in the prescribing literature (9.4%: Carey et al., 2008; 30.6%: Dornan et al., 2009; 5%: Bates et al., 2010; 17.8%: Avery et al., 2012; 20.6%: Seden et al., 2013). In contrast, the findings from this study identified that contraindicated drugs only accounted for 0.9% of errors, no indication for drug given 1.1%, and dose errors 0.8%. These findings were comparable across both INPs and PGD users.

While on the whole medication delivery occurred safely, errors did occur. The overall 8.5% error rate in this study was marginally lower than in three large scale prescribing safety studies, which predominantly focussed on doctors; i.e. medication error rates of 8.9% (Dornan et al., 2009), 12.2% (Avery et al., 2012) to as much as 43.8% (Seden et al., 2013). However, variations in what was defined as an error influence these comparisons, e.g. not documenting patient's past medical history, concurrent medications and allergies was not considered an error by Dornan et al. (2009) and Avery et al. (2012). However, this study regarded the inability to assess the potential impact of a medication on pre-existing conditions as a risk to patient safety, and thus an error in prescribing safety governance. Moreover, Seden et al.'s (2013) study appears to artificially inflate the error rate as their study reported the percentage of prescriptions that had one or more error, and not the actual percentage of individual drug errors. Nevertheless, this study gives overall reassurance that sexual health nurses were comparable to their medical counterparts in prescribing safety. INPs were statistically more likely to make 'moderate' graded medication errors, compared to PGD users. However, errors predominantly related to omitted documentation, which made it difficult to accurately assess medications' potential impact on patients, as opposed

to patients being harmed. However, there were eight occurrences of medication errors categorised by the researcher as unsafe, demonstrating that ongoing medication safety vigilance is indicated. The spread of severity of prescribing errors across 'minor', 'moderate' and 'severe' is consistent with existing literature (Dornan et al., 2009; Avery et al., 2012). This study, therefore, provides evidence that both INPs and PGD users are likely to be comparable to other prescribers with regards to the safe delivery of medicines.

6.4.5 Outcomes of medicines delivery

6.4.5.1 Consultation characteristics

Prioritisation of new episodes of sexual health care, over follow-up, as deemed by the DH (2013) to improve patient access, cost-efficiencies and reduce resources associated with re-attendance. Findings from the clinical notes review identified both INPs and PGD users were comparable with regards to the number of new care episodes managed (70% vs. 67% of consultations, respectively); however, this is less than that reported in sexual health services nationally (i.e. 79%: (PHE, 2017)). Moreover, clinical diary data found PGD users were statistically more likely to manage follow-ups than INPs (47% vs. 30% of their caseload, respectively).

The presence of symptoms increases the complexity of patients' assessment and management (MedFASH, 2014; BASHH, 2017). It was evident from observation data that participants regularly enquired about patients' symptoms. This is important given that the recent integration of online/ postal services is expected to reduce the number of asymptomatic patients presenting to specialist services (London Councils, 2017; SH:24, 2017). However, in line with Black (2012), the findings of this study identified that most patients managed by sexual health nurses were asymptomatic and where patients had documented symptoms, they were statistically more likely to be managed by INPs as compared to PGD users (38% vs. 28% of caseloads, respectively), suggesting INPs managed more clinically complex patients compared to PGD users.

6.4.5.2 Autonomous practice

INPs were statistically more likely to complete care episodes autonomously, compared to PGD users. This contrasts with Black and Dawood (2013) who found no difference in autonomous practice between INPs and PGD users in an emergency department, but is consistent with Courtenay et al. (2015) who found non-INPs frequently needed GP support for prescriptions. The findings of this study identified that the restrictive nature of PGD governance was the primary reason PGD users were unable to practise autonomously; i.e. 46% of INPs' prescriptions would have been restricted had INPs used local PGDs. While PGD restrictions were found to benefit training roles and purposely limit scope of practice, nurse prescribing clearly facilitated autonomous practice for experienced practitioners.

Practitioners working autonomously have less resource and cost implications as they do not need to involve other professional colleagues in managing individual patient caseloads. INPs were less likely to seek medication support from professional colleagues compared to PGD users. When INPs obtained doctors' prescriptions this most frequently related to the legal requirement of doctors signing termination of pregnancy prescriptions (Abortion Act 1967). Conversely, PGD users most frequently sought support for the prescription of antibiotics. Both INPs and PGD users required support for patients' clinical management (which frequently related to management of patients with complex symptoms or presentations outside nurses' scope of practice), which has also been reported previously in the nursing literature (Black, 2012; Wilkinson et al., 2013; Kroezen et al., 2014). Although autonomous practice does facilitate efficient service delivery, particularly as each query required colleagues' time (INP = mean 11minutes; PGD= mean 8minutes), the finding that participants sought support from medical colleagues is reassuring as it highlights nurses' awareness of their accountability, responsibility, team-working and scope of practice.

6.4.5.3 Consultation duration

Although the consultations of INPs were statistically longer than those of PGD users, when adjusted for type of consultation (i.e. new or follow-up), there were no differences found. This is likely due to local clinic processes which schedule a certain number of appointment slots per clinical session. Unsurprisingly new care episodes and the provision of medication increased consultation duration, but there were no differences between INPs and PGDs when moderated for consultation type (i.e. comparing similar consultation characteristics between the groups). Courtenay et al. (2015) identified that INPs spent longer with patients than non-INPs which impacted on the number of patients being managed in general practice; however, the complexity of patients' presentations were not considered as part of this.

6.4.6 Objective 2 summary

Both INPs and PGD users were found to deliver medications frequently, to approximately every second patient. While both groups required a similar range of medications (mostly antibiotics), INPs were more likely to manage more clinically complex patients and deliver medications independently compared to PGD users. Consequently, nurse prescribing was found to be more flexible as nurses' scope of practice increases. While INPs were more consistent at documenting patients' medical risk assessments, PGD users documented 'prescriptions' more thoroughly, and were less likely to make 'moderate' graded medication errors than INPs. Nevertheless, both groups were comparable overall with regards to the safe and appropriate delivery of medicines. Where errors were identified, these predominantly related to omitted documentation, rather than patients being at risk of harm. When observation data were triangulated with documentary evidence, many errors were resolved. However, there were cases where PGD users exceeded the documents' restrictions, and both INPs and PGD users were found to have provided potentially unsafe practice, albeit extremely rarely; ongoing vigilance is therefore indicated. Although INPs were found to practice more autonomously, having the ability to deliver medications through PGDs was found to be highly effective in clinical practice.

6.5 Objective 3

To assess whether and how local application of INP and/ or PGD has benefited patients, health professionals and the NHS, with reference to quality of care, appropriate management of genitourinary and reproductive healthcare, and value for money.

This objective is addressed under six distinct categories:

- Benefits to patients
- Benefits to health professionals
- Benefits to the NHS
- Quality of patient care
- Appropriate management of genitourinary & reproductive care
- Value for Money

6.5.1 Benefits to patients

INPs and PGD users reported that patients benefited from safer, better-informed, efficient services because nurses could independently deliver medications. In turn, patients reported extremely high levels of satisfaction with their medication consultations, with no differences found between INPs and PGD users. Patients clearly valued nurses' approachability; had confidence in their clinical management; were highly satisfied with medication explanations; and were given opportunities to ask questions. Positive patient feedback is a consistent finding in the general nurse prescribing literature (Drennan et al., 2011; Stenner et al., 2011; Bergman et al., 2013; Tinelli et AL., 2013, Courtenay et al., 2017b), as is patients' confidence in nurses' consultation skills and medication knowledge (Courtenay et al., 2010; Dhalivall, 2011; Banicek, 2012; Bergman et al., 2013; Ross et al., 2013; Courtenay et al., 2015). Interestingly more than half of patients were unaware nurses independently delivered medications, but those that did, were confident in nurses' abilities.

The initial PPI feedback that informed this study's design, identified patients' main medication concerns related to side effects, reluctance in taking medicines, and medication effectiveness. This is in-line with other nurse prescribing literature (Banicek, 2012; Riley et al., 2013). While observational data highlighted both INPs and PGD users addressed these concerns, findings based on observational evidence highlighted less information was provided with regards to

‘reliable sources of information’ and ‘what to do if there are any concerns about the management of their condition’. However, this was not consistent across all observed practitioners.

Satisfaction with medication information

Patients in this study were also very satisfied with the level of medication information received, with responses to the Satisfaction with Information on Medication Scale’s (SIMS) scoring positively (i.e. ‘about right’ or ‘not applicable’). This demonstrated from the patients’ perspective that investment in both INP and PGDs was an effective use of resources. Patients were marginally more satisfied with the information received about action and usage of medications (i.e. its name, how to take it, how much and when) than the potential problems (i.e. what to do if the forget a dose, potential side effects, what to do if they experienced side effects, and concurrent use of other medications). This is in-line with Latter et al. (2007d), these researchers suggesting that prescribers inadvertently focusing on medication usage, rather than their associated risks, may encourage adherence by avoiding mentioning the negative aspects of medications. It was evident from the findings of this study that when patients were less satisfied with medication information, this most frequently was associated with concurrent alcohol use (26%); whether the medication would cause drowsiness (24%); and side effects (18%). As many sexual health related drugs are unlikely to be affected by moderate alcohol use, or cause drowsiness (BNF, 2016; Local handbook, 2016), nurses may have been less inclined to routinely discuss these issues. Moreover, nurses may have been unfairly criticised here. If the SIMS had not specifically asked about these areas, patients may not have considered them necessary information, particularly as patients otherwise reported opportunities to ask questions in the first section of the patient experience questionnaire.

6.5.2 Benefits to health professionals

It was evident from the findings that INPs and PGD users considered that the ability to deliver medication was essential for their roles, increased satisfaction and confidence, and facilitated

holistic autonomous practice. Moreover, INP and PGDs provided the 'freedom and confidence' (Participant 4) to safely manage patients. Despite PGDs' restrictive nature, many nurses (and services) were content using them. PGDs were reported to complement clinical roles and provide enough scope for those who did not want to undergo INP training. The personal and professional benefits highlighted also included improved job satisfaction, self-esteem, specialist knowledge and clinical assessment skills. Similar health professional benefits have been reported elsewhere in the nurse prescribing literature (Stenner and Courtenay, 2008; Wilkinson et al. 2013; Carey et al., 2014; Courtenay et al., 2017a). The additional stress, and accountability and responsibility associated with delivering medications were highlighted as potential barriers to independent medicines delivery. Moreover, the intensity of the INP training was regarded as a major barrier. This was particularly evident in those not academically orientated, and those unwilling or unable to invest a large amount of personal time in the training programme who had managers unwilling, or unable, to invest time and/ or resources. INPs also had to invest a significant amount of their personal leisure time in completing the university training course, which was not found in the PGD user cohort. Although INPs' personal investment is unlikely to be recompensed (Hobson et al., 2010; Earle et al., 2011), INPs were more frequently on higher salaries compared to PGD users which suggested personal investment in the INP course could improve their career prospects; therefore, as the NHS is funding university fees and providing study leave, it is not unreasonable to expect nurses' personal commitment and time to achieve such long-term benefits. However, the differences in salary cannot be solely attributed to whether nurses used INP vs. PGDs. Higher salaries/ banding for INPs has also been found in other literature, compared to those who could not prescribe (Kroezen et al., 2012; Courtenay et al., 2015; Creedon et al., 2015); however, Kroezen et al. (2012) identified that this often related to other academic achievements and not the ability to prescribe.

The professional benefits of INP and PGDs expanded beyond nurses. Findings identified that although medical colleagues were initially hesitant about nurses delivering medicines independently, they were reported now to be consistently supportive. This is in line with findings of a national survey of non-medical prescribers in Wales (Courtenay et al., 2017a). In fact, where nurses were unable to provide medication independently, doctors commented on the service delivery impact, and would complain to senior nurses about efficiency and productivity. Findings

from this study are in-line with the general consensus of nurse prescribing literature with regards to: enhanced nurse-medical relationships (Bradley and Nolan, 2007; Earle et al., 2011; Ross, 2015, Hopia et al., 2016; Lim et al., 2017); a reduction in nurses seeking prescriptions (Courtenay et al., 2009b; Price et al., 2012; Wilkinson et al., 2013); and doctors' increasing confidence in the ability of nurses to manage more clinically complex cases (Wilkinson et al., 2013; Ross, 2015; Hopia et al., 2016).

6.5.3 Benefits to the NHS

It was evident from the findings that INP and PGDs supported efficient service delivery through improved capacity, access to services and a more streamlined patient journey. These findings are consistent with the wider nurse prescribing literature (Courtenay et al., 2010; Jones et al., 2010; Courtenay et al., 2011; Price et al., 2012; Wilkinson et al., 2013; Carey et al., 2014; Creedon et al., 2015; Ross, 2015). There was also significant support for medication delivery from INPs and PGD users with regards to supporting service delivery. The findings also identified that nurses' independent delivery of medications facilitated the creation of nurse-led clinics. Although senior participants reported that they preferred INP over PGDs (primarily because clinical presentations often exceeded PGDs' restrictions), as PGDs are locally governed they can be amended to reflect practice need (NICE, 2013).

While there are clear NHS benefits for independent medicines delivery by nurses, resource barriers were also highlighted. INP barriers related to the cost of the training course, the release of staff for university training days, and doctors' Designated Medical Practitioners' (DMP) time (discussed further under 'Value for money'). Barriers reported in relation to PGD governance was its laborious and time-consuming nature and complexity. Such barriers have been reported previously (Price et al., 2012). It was also apparent from the findings that the chair of the non-medical prescribing committee heavily influenced the approvals process for both PGDs and INP. The influence of these committees over nurses' independent delivery of medication, has been reported previously (Dobel-Ober and Brimblecombe, 2016). The local influence of non-medical prescribing committees was further demonstrated in this study with regards to one site requiring

qualified INPs to maintain detailed personal portfolios of each drug they intended to prescribe. Not only did this create a barrier to practice, it made INPs revert back to using PGDs, undermining the benefits associated with being a qualified prescriber.

6.5.4 Quality of patient care

It was evident from the findings that there were no differences in the quality of care provided between INPs and PGD users. Based on documentary and observational data, nurses performed well on taking appropriate clinical histories and assessments; interpreting relevant investigations, understanding the conditions being treated, and how to effectively manage them. The observational findings also highlighted that both INPs and PGD users consistently listened to patients and sensitively managed their concerns. This is consistent with the findings on nurse prescribers working in the area of diabetes (Courtenay et al., 2009b). In the eight cases where quality of care was suboptimal (see section 5.9.15 on page 180) incidents were reported and investigated in line with local protocols, including patients being informed and corrective actions taken. Based on documentary evidence there were no known official patient complaints. Ultimately, patient's experience is a key indicator of quality of care, and patients in this study reported very high levels of satisfaction with care. Moreover, content analysis of patients' questionnaires clearly identified a high quality of care, with participants commenting on the excellent service, and knowledgeable and friendly/ approachable staff. Observational data supported this finding with nurses interacting with patients in a non-judgemental manner, and patients appearing comfortable talking about their sexual health with the nurse.

6.5.5 Appropriate management of genitourinary and reproductive healthcare

6.5.5.1 STI diagnoses and management

Chlamydia, genital warts, gonorrhoea, non-specific genital infections and the management of sexual partners of those with infections were those most commonly diagnosed and managed by

INPs and PGD users in this study. This concurs with national evidence (PHE, 2017). It was evident from the findings that PGD users were involved in the management of 27 diagnosed conditions and INPs 25 conditions (i.e. INPs had no patient presentations involving *Trichomoniasis vaginalis* or Hepatitis C management) i.e. most of the sexual health diagnoses reported in national data (PHE, 2017). Ongoing management of people living with HIV was not routinely undertaken as part of sexual health nurses' roles within this study (however, some senior nurses did have dual sexual health & HIV roles). It was evident from the findings that these conditions were appropriately managed by INPs and PGD users, and, where appropriate, support was sought from doctors.

6.5.5.2 Reproductive healthcare

Navigating the wide range of contraception choices, their benefits and potential risks can be a challenging process for patients and healthcare workers (FSRH, 2017). However, observational data demonstrated that both INPs and PGD users appropriately discussed the range, risks and benefits of contraception methods with patients. In cases where patients' contraception choices were contraindicated, the reasons for these contraindications were discussed with patients and appropriate options provided. It was evident from the findings that both INPs and PGD users appropriately delivered a range of advice, education and contraception methods (e.g. oral contraceptive pills, patches, long-acting reversible contraceptives). Both groups also managed termination of pregnancies alongside doctors. The only contraception method not managed by INPs and PGD users in this study was sterilisation. This demonstrates the extensive range of skills INPs and PGD users have with regards managing patients' reproductive healthcare.

It was evident in both genitourinary and reproductive observed practice that INPs and PGD users had advanced levels of knowledge and skills that enabled them to work autonomously and confidently with patients.

6.5.5.3 Non-provision of medication

The findings highlighted a total of 126/1,682 cases where medication was indicated, but not delivered. Of these cases this was appropriate in 101 cases, most of which related to the medication not being delivered due to the condition not being a sexual health condition, or, the decline of treatment by patients until pathology results were available. There were a further 25 cases in which the treatment indicated was not offered. These cases included situations in which prophylactic medicines had not been offered to patients at recent risk of pregnancy, patients at high risk of STIs, or patients who could have been protected through vaccination programmes (e.g. hepatitis B). While the cost of the drugs were saved in these circumstances, the long-term consequences of not providing medications in these circumstances could potentially lead to health outcomes that are expensive to manage in the future (e.g. managing hepatitis B infection).

6.5.5.4 Unplanned re-attendances

A total of 306 (18%) patients re-attended services within three months. The most common reason (33%) for this was a positive diagnostic test. Other reasons included the development of new symptoms, or patient behavioural issues (such as unprotected sex with an untreated partner and re-infection with an STI) that required re-treatment. Therefore, it is unlikely that re-attendance in these circumstances was linked to inappropriate practice; particularly given that re-infection from untreated partners is a common occurrence (BASHH, 2015). Medication-related re-attendances most frequently involved unresolved/ worsening/ returned symptoms (n=34, 11%), side effects to medications (n=31, 10%) or issues with long-acting reversible contraception (n=20, 6.5%). Despite approximately one fifth of patients returning within a three-month period, there was no indication that this was attributed to the level of care provided by INPs or PGDs users.

6.5.6 Value for money

It was evident from the costs and consequences analysis (CCA) that many clinic processes had no statistical differences between INPs and PGD users, and therefore, both methods were beneficial. However, consideration of which method offers the better value for money is less clear cut as value for money does not necessarily mean least expensive. The primary cost differences

between the groups were attributed 'training and governance'; however, the INP training costs may be over-inflated as much of the DMP staffing resources were likely provided during existing clinical responsibilities (see section 6.6.2.7 Costs). While PGDs were able to be used by multiple staff members at relatively small investment, they were considered difficult to govern, required frequent revalidation and were restrictive in practice. Whereas INP offered flexibility and streamlining of service delivery but involved significant investment from the NHS and individual nurses. INPs subsequently managed more complex cases and required less professional support from colleagues compared to PGD users; however, when INPs did require support they required it for longer duration than PGD users (11 minutes vs. 8 minutes, respectively), further suggesting INPs managed more complex patients. Courtenay et al. (2015) also found that nurses who could not prescribe sought support more frequently than INPs, however, the additional support obtained incurred less additional cost than the longer consultation duration and higher banding of INPs. In this study, there was no difference in consultation duration, but comparably, INPs were on higher bands than PGD users. However, as this study demonstrates, the impact INP has on service delivery and the flexibility to manage increasingly complex patient presentations provides long-term returns for the NHS.

As such initial INP training investments can be discounted over the term INPs continue to prescribe, and further discounted if the skill is used frequently. While PGDs were comparably less expensive, they were impractical to write for every type of sexual health presentation and for every drug required. Consequently, PGDs offered best value for money when nurses worked with predictable and frequent patient presentation types but as nurses' scope of practice increased INP was more useful in clinical practice. However, the investment required for nurse prescribing training concerned 40 INP interviewees, with regards to the sustainability of funding for university courses, and, to save money, they were concerned the NHS would revert to using PGDs (Carey et al., 2014). This indicates that further assessments are required on the costs and consequences of nurses' medication delivery.

While the costs associated with training are important factors as NHS nursing education budgets are becoming restricted, the priority should remain on the value added benefits associated with investments. As clearly demonstrated nurses' independent access to medication has benefits to service delivery, nurses' roles and for improved patient outcomes, which are important aspects of

nurse education and training investment (Willis, 2015). Moreover, with regards to value added benefits of INP, nurses unlike doctors (where prescribing is included in undergraduate training), require additional postgraduate training investment to prescribe. Therefore, when comparing costs, consequences and value added benefits further research into comparing INPs with doctors may demonstrate that INP training is not as expensive as it appears when compared with PGD governance.

6.5.7 Objective 3 Summary

The implementation of both INP and PGDs have benefited sexual health patients, health professionals and the NHS, allowing nurses to provide high quality, appropriate genitourinary and reproductive healthcare. Patients have benefited from a safer, better informed, efficient service because nurses were able to use INP or PGDs. Although a small number of patients were dissatisfied with regards to the information they received on medicines' side effects, most patients were very satisfied with this information and the overall nurse consultations. From the staff perspective, there were many personal and professional benefits highlighted for using INP and PGDs, but the training requirements for INP and PGD users created barriers. The NHS was found to have invested significant costs and resources into INP and PGD training and governance, with the consequences of this investment leading to efficient, accessible sexual health services with smoother patient journeys. Moreover, INPs and PGD users were skilled to such a level they were able to appropriately manage an extensive range of genitourinary conditions and reproductive healthcare interventions required of modern day sexual health services. However, INP training was considered a more effective investment than PGDs as nurses' scope of practice increased as INP facilitated more autonomy.

6.6 Study limitations and implications

6.6.1 Representativeness of study

6.6.1.1 Sites

The study's findings were based on five NHS sexual health services across England, Scotland and Wales. Three operated solely from city centre locations, and the other two provided additional outreach services. Consequently, rural and primary care services were underrepresented in this study; however, the focus was on specialist level 3 sexual health providers (which are predominantly situated in cities). In line with NHS Framework (2013), all services were in the process of integrating, or had fully integrated, genitourinary and reproductive healthcare (previously distinct specialities).

6.6.1.2 Nurse participants (across all methods)

The clinical notes review represented practice from all the INPs, and 87% (58/67) of PGD users that were invited to complete the staff questionnaire. However, PGD users were underrepresented in the staff questionnaire overall compared to INPs (response rate 52% vs. 93%, respectively). Nevertheless, as both INPs and PGD users' questionnaire response rates exceeded 50% in line with guidance (Moule and Goodman, 2009), they were considered representative. As potential participants who used the clinical diary were aware that the diaries were to be used to explore medication delivery practice, nurses who volunteered to participate were more likely to be more confident and experienced practitioners. By contrast, the clinical notes review included the patients of all INPs or PGD users. Therefore, while the clinical notes review provided an overview of actual practice, the clinical diary was more likely to compare clinically confident PGD users with similarly confident INPs. The consultation observations involved a non-randomised, convenience sample of nurses and patients who volunteered to participate, which allowed unique and privileged insights into nurse-patient interactions but may have altered participants' behaviour as detailed by the 'Hawthorn Effect' (Moule and Goodman, 2009; Creswell, 2014).

6.6.1.3 Patients

While the patient experience questionnaire yielded a high response rate (93%), only 49% of eligible patients were offered the questionnaire as a result of it failing to be distributed to them by nurses, or, the patients declining the invitation to participate. The findings may, therefore, not be truly representative of patients' experience.

6.6.2 Study methods and design

6.6.2.1 Staff interviews

Although staff interviews provided an in-depth exploration of independent medication delivery practice and processes, only a small number of participants were interviewed, therefore, findings may not be representative of the wider population.

6.6.2.2 Staff questionnaire

Although the staff questionnaire was deemed to have face and content validity (due to its design, as presented in section 5.4.2), it was not tested for validity or reliability which affects confidence in its ability as a research tool (Parahoo, 2006; Bowling, 2009; Moule & Goodman, 2009). Moreover, during data collection two issues became apparent with regards to the attitude statements in Section 2. Firstly, the 'likert-type scales' were not intermingled with positive and negative-worded statements. This left Section 2 open to "rhythm…ticking boxes in the same column" (Parahoo, 2009, p.294). Secondly, there was a transcribing error which asked PGD users about 'prescribing' rather than 'medication delivery'. This may have confused respondents, which possibly explains why three PGD users did not answer this specific question.

Section 3 of the questionnaire (which explored costs) was limited as it relied on nurses' recall and estimations on training resources, which may have been used years earlier. Therefore, the costs are not accurate representations of expenditure (i.e. may be over or under estimations), rather, they provide an indication of the resource differences between INP and PGDs. Furthermore,

several questions within section 3 were not completed by all respondents and so may not be truly representative of the sample.

6.6.2.3 Patient questionnaires

Although the questions used in the patient experience questionnaire were based on validated tools, there were some limitations which may have affected their overall validity. The questions designed to explore consultation satisfaction only (out of the 38 from the original validated tool (Weston et al., 2010)) that were deemed by the researcher as relevant for this study. There were three further issues associated with the SIMS tool that became apparent during data collection. Firstly, question 8 (i.e. “how to use your medication?”) was inadvertently omitted during design of the questionnaire. Secondly, the presentation of the SIMS tool in this study used a 1 to 5 numbered scale to represent responses to questions. This could have been misinterpreted as a Likert scale. The use of dots, instead of a scale, would have been a more appropriate way to present this tool. Thirdly, some of the SIMS’s questions relating to adverse medication effects, may have unfairly criticised information provided by clinicians, particularly if the adverse effect was not relevant to the medication that was delivered, e.g. many drugs used in sexual health are unlikely to cause drowsiness, therefore, and it is unlikely to be routinely discussed, unless the patient asks. Consequently, the SIMS may be better applied, in some clinical areas, if questions not relevant to the medication supplied are not integral to the scoring.

6.6.2.4 Clinical diary

The clinical diary required nurses to remember to complete entries and code responses. While overall this was done well, multiple data points were omitted by participants. Moreover, data entries on consultation durations, and time spent with other professionals could have been over or under estimated and were frequently missing. While overall the diary yielded valuable data, in-line with Moule and Goodman’s (2009) methodological suggestion, it complimented the other data collection methods, but would not have been a suitable standalone method.

6.6.2.5 Clinical notes review

The original study design intended to use the clinical diary to source patients' records for the clinical notes review. However, it became apparent that the minimum sample size quota would not be achieved using this method. This limitation subsequently strengthened the overall study design as sourcing of clinical notes was amended to come from patient attendance lists instead of the diary. Consequently, data collection became standardised between the five participating sites (in terms of dates) and explored actual practice rather than being limited to nurses who volunteered to participate in the diary. Nevertheless, relying on data not collected specifically for research was an issue as the clinical records only represented what was documented, rather than actual practice. Omitted documentation was the main limitation of using clinical records, and at times impacted on the researcher's ability to draw conclusions. Moreover, there were difficulties in locating clinical notes in 2 out of 5 sites. In site 2 patient attendance lists could only be aligned to patients who received medication. Site 5 were unable to align patient attendances to those managed by nurses. Subsequently, each record had to be individually checked to determine which clinician managed the episode. Due to time constraints, it was not possible to obtain site 2 & 5's minimum quota for 'INPs care episodes where medication was not given'. To achieve these minimum sample size quotas within the study time frame, the clinical diary was used to source the remaining 18 records required. Overall, a total of 3,052 clinical records had to be reviewed by the researcher to achieve the 1,682 clinical records included in this study, which proved to be a time consuming and labour intensive task.

A further limitation of the clinical notes review involved the researcher interpreting practice at sites with which they were unfamiliar. To strengthen the design, all aspects of substandard care/ documentation were confirmed with a local representative. Moreover, 10% of medication delivery records were independently checked by a local representative. However, there were some minor variations between the researcher and the independent reviewer. Most of these variations related to omitted documentation i.e. the researcher determined that a lack of documentation made aspects difficult to accurately assess, whereas local representatives were confident they understood patients' management based on what was documented.

6.6.2.6 Observational study

While the researcher endeavoured not to influence practice, his presence, including participants' awareness of audio-recording, was likely to have modified behaviour. This was, in some way, mitigated with nurse participants by undertaking multiple observations with the same nurse, behaviour change reported to be difficult to maintain for prolonged periods (Moule and Goodman, 2009; Creswell, 2014). Moreover, the researcher's presence may have affected patients' ability to fully discuss their health concerns. A further limitation of this method was that audio-recording was used instead of video-recording. Consequently, subtleties and non-verbal communication may have been over-looked. This also made double checking the researchers' interpretation difficult.

6.6.2.7 Costs

The costs analysis used a descriptive approach which is generally considered the norm for exploring service delivery interventions (Sutton et al., 2018).The case study design limits the generalisability of the findings. There was some variability in practice between the research sites which was not explored in depth within the remit of this study as the focus was on an overall comparison between INP vs. PGDs. Therefore, the findings may not be generalisable to all sexual health services.

It was evident from the findings that the resource implications of INP training and governance were significantly higher than those of PGD governance. However, it should be borne in mind that INP costs included time INPs spent with their DMPs as an additional resource. It is expected that INP students undertook much of the DMP supervision alongside their normal clinical duties, with their DMP being available as required (perhaps providing medication discussions at the end of clinics). Therefore, the DMP clinical supervision is unlikely to have incurred the full additional resources, time or costs reported. It was also evident from the findings that not all INPs obtained the full 12 DMP clinical supervision days expected as determined by the NMC (2015). A further consideration for INP training costs relates to the allocation of study days for attending university. Costing of study days was based on respondents' current banding; however, respondents may have been on a lower band at the time of INP training. A further consideration, which was not

captured in this study, was the resources and costs associated to backfill while undertaking INP training which may increase costs or affect the provision of service delivery. There may also be cumulative costs associated with INP training which includes PGD training as 22 (85%) INPs reported using PGDs prior to becoming prescribers.

Sections on PGD governance are very limited as the researcher was only able to track the process at one single time-point from one site. While the researcher's input was logged, other stakeholders may not have been as diligent with the time they spent reviewing PGD documentation. Moreover, the researcher was a member of the non-medical prescribing committee and knew the PGD approval process very well. Someone less informed may have taken longer to navigate the pathway. Further tracking of multiple PGDs are required to obtain a more accurate cost assessment for PGD governance.

Medication costs presented were based on BNF 2016 prices, but local services may have negotiated better prices. However, this is unlikely to impact on the findings as there were no statistically significant differences in the therapeutically appropriate delivery of medications.

6.6.3 Implications for practice

Findings from this research have several potential implications for policy and practice from the perspective of the NHS, managers and individual nurses.

NHS perspective

This study has demonstrated that the independent delivery of medication is an essential component of the sexual health nurse practitioner role. Consequently, it is essential that the NHS continues to provide funding and professional support to facilitate medication delivery training, integration and CPD. Where clinically appropriate, nurse practitioners should be offered the opportunity to become INPs to support service delivery, patient experience and enhance nurses'

skills. While INP was found to offer greater flexibility and responsiveness to patients' requirements, PGDs clearly offered medication delivery benefits for nurses not willing, or able, to become INPs. Moreover, PGDs were also found to support junior staff training to become autonomous practitioners prior to undertaking INP roles. As both INP and PGDs facilitate autonomous practice doctors' time can be released to allow doctors to manage more clinically complex patient presentations. Therefore, ongoing clinical integration of both INP and PGDs are indicated within sexual health.

With regards to PGDs, it was evident that a great amount of variability existed in a small number of sites with regards to how PGD training was conducted and how nurses were deemed competent to use PGDs. To provide greater structure and consistency for PGD training, it is recommended that the NHS creates a national standardised PGD training and assessment programme. This could be divided into two parts. Part 1 providing information on general PGD legislation and use, and Part 2 tailored to provide speciality-specific medication training. Part 2 could be created in collaboration with NHS-approved clinical speciality working groups to align PGD training with the relevant national standards and guidelines. These same speciality working groups could also write, approve, and update national PGDs that could be adaptable for local use. For example, PGD documents could be designed so their indications for use and exclusions were optional to allow local services to customise how they were used in clinical practice. Moreover, if the overall oversight of the PGDs were at a national level, this would standardise both training and practice and also streamline processes for creating, maintaining and updating PGDs.

NHS managers' perspective

The study's findings identified a number of issues which had implications for practice from a manager's perspective. These included (i) considerations of nurses' scope of practice and what access to medication is required; i.e. PGDs or INP (ii) the use of PGDs outside of their restrictions; (iii) and incomplete documentation. With regards to access to medication, managers need to

ensure nurses have the correct access to medication as required by the local patient population and service delivery model. PGDs were used outside of their restrictions by participants in this study. It is, therefore, important for managers to ensure that medication delivery method(s) are fit for purpose and undertaken safely and appropriately. Furthermore, the incomplete documentation identified in this study highlights the need for improvement in documentation skills. This could be achieved through discussions in local team meetings, appraisals and routine documentation audits or increased use of electronic proformas.

Nurses' perspective

While the NHS local managers have a responsibility to support nurses delivering medications, ultimately, individual nurses have accountability and responsibility over their own practice. Consequently, nurses should ensure they are aware of their scope of practice and understand the implications of delivering medications. The NHS has restricted educational budgets, and therefore, nurses should seek CPD such as self-directed learning, peer teaching, journal clubs and engagement with organisations and professional communities involved in creating national guidelines (e.g. BASHH or FSRH).

6.6.4 Future research

This study has explored nurses' medication delivery in sexual health and confirmed the safety and appropriateness of INP and PGD use within this speciality. However, further exploration of medication safety is required across other specialities and professions, particularly as the non-medical prescribing powers are being widened to other healthcare professional groups. This study design could be repeated in other clinical areas, specifically those that utilise more complex drug regimens (e.g. chemotherapy), or where patients frequently have multiple co-morbidities and/ or polypharmacy. Moreover, as nurses have become independent practitioners in their own right, further research into how INP compared with doctors' prescribing practice, and how nurses' advanced clinical skills have changed the roles of both professions is indicated; for example (i)

Are nurses becoming maxi-nurses or mini-nurses? (ii) How do professional models of care (nursing vs. medical) influence consultation skills, patient care, patient experience and prescribing practice?

There is limited evidence that has explored the benefits and resources of nurses working in advanced practice roles. In the studies that are available (Norman et al., 2010; Courtenay et al., 2015) the findings go against expectations that nurses in advanced practice roles offer greater cost-effective healthcare delivery. As INPs in this study were also found to be more expensive, further research into the resource and cost implications of nurses working in autonomous roles is required throughout a range of advanced practice skills and clinical areas. It should be borne in mind that cost should not always be the primary focus rather the value added benefit of nurses working in advanced practice roles.

Another area for research includes further in-depth interviews and focus groups with NHS stakeholders to (i) provide a deeper analysis of their perceptions of medication delivery governance, (ii) formulation of a more streamlined approach to approval of INP and PGDs from an organisational, departmental and individual's perspective, (iii) support standardisation of governance, training and assessments in medication delivery across organisations and the NHS.

6.7 Conclusion

The robust multiple mixed methods approach employed throughout this study has generated new epistemological and ontological knowledge with regards to how INP and PGDs influence sexual health nurses' practice from: experts in the field; detailed empirical research methods; and the exploration of how nurses work for the well-being of patients, the NHS and themselves. It was evident throughout this study that independent access to medication is fundamental to the modern sexual health nurses' role. Moreover, INP and PGDs have facilitated a paradigm shift for nurses, moving from doctors' handmaidens to autonomous advanced clinical practitioners who independently manage patient care episodes, run their own clinics and hold high levels of academic achievement (i.e. Masters Degrees and PhD). Consequently, nurses were found to hold a range of positions, from providers of day-to-day service delivery to advanced practitioners, to clinical leaders, researchers and innovators to those that hold senior strategic policy making and governance positions. While limited to sexual health, when considered against the existing literature, it is expected the findings from this study can be generalised to other specialities where nurses autonomously manage patient care episodes.

This study found a highly comparable level of clinical practice between INPs and PGD users with regards to the range of conditions managed and medications required. However, INPs were found to be more responsive, autonomous and flexible in delivering medications compared to PGD users. Moreover, INPs, as compared to PGD users, often benefited by working at higher salary bands, but this cannot be solely attributed to becoming an INP. The benefits and barriers between INP vs. PGDs varied between sites and individual nurses. While most NHS stakeholders regarded PGDs as both cumbersome and time-consuming to govern, in-line with their purpose (NICE, 2013), PGDs were less expensive to incorporate within clinical teams and were highly suitable for situations where patients had predictable presentations. However, as nurses began to manage more clinically complex presentations, the restrictive nature of PGDs was apparent, and INP enabled nurses to work more autonomously and be responsive to patients' medication needs. Nevertheless, PGDs offer a suitable alternative to INP where nurses cannot, or do not wish to, become prescribers.

Given the trailblazing approach the UK has, to providing non-medical healthcare professionals with independent access to medications, this study has further re-enforced the safety, appropriateness and professionalism that nurses have with regards to their medication delivery powers. Such findings should provide additional reassurance to other countries looking to expand legislation with regards to non-medical prescribing. Moreover, this study has also demonstrated that specialist sexual health nurses are comparably as safe as their medical counterparts (of note this study employed stricter criteria for 'errors' in comparison to other studies; however, this study was within a specialist area while previously doctor comparisons were usually based on evidence from more generalised settings). Consequently, further consideration should be given to: how nurses' medication access has influenced the nursing and medical roles/ relationship; the effects on patient interactions and outcomes; and the impact on service delivery. These are important considerations, in order to determine the value added benefits of how INP and PGDs facilitate nurses in managing increasingly complex patient presentations, and how nurses' practice compares with that of their medical colleagues. Such exploration of value added benefits would be meaningful given the apparently substantial cost differences reported between INPs and PGD users (which may provide over-inflated comparisons that deter NHS managers from embracing INP within their services). Nevertheless, both INP and PGDs were found to be highly suitable, safe and valued by patients within the sexual health services studied.

6.8 Post-script: about the researcher and his PhD journey

I qualified as a nurse in 1999 and worked in sexual health nursing since 2002 in various roles including staff nurse, charge nurse, health practitioner, nurse practitioner and consultant nurse. Through my advanced clinical practice roles, I became more inquisitive with regards to evidence based practice, the development of clinical guidelines and auditing performance against standards of practice. I became a qualified INP in 2008. During my INP training I had noted that there was limited literature on advanced practice in sexual health, and despite a growing non-medical prescribing evidence base, I felt more research was needed with regards to its clinical application. Subsequently, I used my NIHR Masters of Research in clinical practice fellowship in 2010 to explore how nurse practitioners delivered medication in sexual health and accident and emergency. That project formed the basis of this study and also created a personal academic interest with regards to how nurses work at advanced levels, particularly related to medication delivery.

This project was further shaped through my consultant nurse clinical role. I often attended meetings with senior NHS stakeholders, and I noticed three key components that were raised frequently: (i) how aspects of care were integrated within clinical practice and how safe were they? (ii) What was the patient experience of using the service? (iii) How much did it cost and could we make savings? Therefore, to ensure this study had relevance back to clinical practice, I considered these three themes essential components when designing this project. Also within the consultant nurse role I experienced first-hand how ‘cumbersome’ and ‘stressful’ the PGD governance, approval and training process could be.

This project was awarded funding as part of an NIHR/ HEE clinical doctoral research fellowship. Given the opportunities associated with the training fellowship, I was very keen to experience undertaking different research methods while receiving expert supervision. While I feel the project warranted the multiple mixed methods approach, I also personally benefited from practically experiencing the strengths and weaknesses of the various methods adopted throughout this study. Although it presented challenging issues by creating vast amounts of data and how best to present the findings, I feel the experience has prepared me to undertake various types of

research projects in the future. However, I would seek more efficient processes to obtain the required data (e.g. avoiding the need to review 3,000 sets of notes).

While undertaking this PhD process I greatly valued the expertise in the team around me, the level direction provided by my supervisor team and support from colleagues, family and friends. One colleague did pass on some great advice: '*if something is taking you a long time, then there is probably an easier way to do it*'. This was never as true as when I considered the weeks and months I was undertaking data analysis doing multiple calculations on Microsoft Excel®, and then my statistician repeated many of my calculations in SPSS® in just a few clicks. While this gave me confidence in the accuracy of my calculations, I have learned to go to the person who knows much sooner to save a lot of unnecessary work.

The main aspect that I have taken from this project is how willing people were to support me and how generous they were with their time. This was particularly evident at the research sites where nobody knew me, yet many colleagues were very proactive and extremely welcoming. Sometimes this went beyond participation in the project. One such example of kindness was when I was camping for a week during data collection as all the hotels were fully booked and staying in the 5-star luxury spa hotel would have exceeded my entire subsistence budget. Upon hearing I was staying in a tent (which I rather enjoyed) many of the team offered their spare rooms. While I was very touched, I politely declined; however, one nurse was adamant that I came over for dinner to ensure I had at least one home cooked meal. I have very fond memories from all the sites and I'm forever grateful to everyone who supported me.

Throughout this process people often commented to me that you must be really intelligent to undertake a PhD. I do not feel that is the case, rather to complete a PhD I feel you need to be able to focus on a single topic for a very long time, take direction well, take criticism constructively, smile and trust in your own expertise and in that of your team. This has been a difficult but rewarding journey that has provided me with the tools and experience to continue my clinical academic nursing career well into the future.

References

Ahuja, J. (2009) 'Evaluating the learning experience of non medical prescribing students with their designated medical practitioners in their period of learning in practice: Results of a survey', *Nurse Education Today,* 29(8), pp. 879-885. [Online]. Available at: https://doi.org/10.1016/j.nedt.2009.05.004 (Accessed: 12 May 2015).

Aronson, J.K. (2004) 'Editor's view: Rational prescribing, appropriate prescribing', *British Journal of Clinical Pharmacology*, 57(3), pp. 229-230. [Online]. Available at: http://onlinelibrary.wiley.com/doi/10.1111/j.1365-2125.2004.02090.x/pdf(Accessed: 12 May 2015).

Avery, T., Barber, N., Ghaleb, M., Dean-Franklin, B., Armstrong, S., Crowe, S., Dhillon, S., Freyer, A., Howard, R., Pezzolesi, C., Serumaga, B., Swanwick, G. and Talabi, O. (2012) 'Investigating the prevalence and causes of prescribing errors in general practice: The PRACtICe Study.' [Online]. doi: 10.3399/bjgp13X670679 (Accessed: 12 May 2015).

Aveyard, H. (2014). *Doing a Literature Review in Health and Social Care a practical guide*. 3rd ed. Maidenhead, Open University Press.

Baileff, A. (2007). Patient group directions in walk-in centres. *Primary Health Care,* 17(5), 36-39.

Banicek, J. (2012) 'Attitudes of postoperative patients towards hospital nurse prescribing', *Nurse Prescribing,* 10(12), pp. 612-618.

Bates, K., Beddy, D., Whirisky, C., Murphy, M., O'Mahony, J.B. and Mealy, K. (2010) 'Determining the frequency of prescription errors in an Irish hospital', *Irish Journal of Medical Science,* 179, pp. 183-186.

Bayliss, D. (2012) 'Safe prescribing for nurses', *Practice Nurse,* 42(13), pp. 23-24.

Bergman, Karin; Perhed, Ulla; Eriksson, Irene; Lindblad, Ulf and Fagerström, Lisbeth (2013) 'Patients' satisfaction with the care offered by advanced practice nurses: A new role in Swedish primary care', *International Journal of Nursing Practice*, 19(3), pp. 326-333

Berry, D., Bradlow, A. and Courtenay, M. (2008) 'Patients' attitudes towards, and information needs in relation to, nurse prescribing in rheumatology', *Journal of Clinical Nursing,* 17(2), pp. 266-273.

Bhanbhro, S., Drennan, V.M., Grant, R. and Harris, R. (2011) 'Assessing the contribution of prescribing in primary care by nurses and professionals allied to medicine: a systematic review of literature', *BMC Health Services Research* 11(330). [Online]. Available at: https://bmchealthservres.biomedcentral.com/track/pdf/10.1186/1472-6963-11-330 (Accessed: 12 May 2015).

Black, A. (2012) 'Non-medical prescribing by nurse practitioners in accident & emergency and sexual health: a comparative study', *Journal of Advanced Nursing,* 69(3), pp. 535-545.

Black, A. and Dawood, M. (2013) 'A comparison in independent nurse prescribing and patient group directions by nurse practitioners in the emergency department: A cross sectional review', *International Emergency Nursing, 22*(1), pp. 10-17.

BNF: British Medical Association and Royal Pharmaceutical Society of Great Britain (2016). *British National Formulary.* 71st edn. UK: BMJ Publishing Group.

Bradley, E. and Nolan, P. (2007) 'Impact of nurse prescribing: a qualitative study', *Journal of Advanced Nursing*, 59(2), pp. 120-128.

Bradley, E., Campbell, P. and Nolan, P. (2005) 'Nurse prescribers: who are they and how do they perceive their role?', *Journal of Advanced Nursing*, 51(5), pp. 439-448.

Bradley, E.; Hynam, B.; Nolan, P. (2007) 'Nurse prescribing: Reflections on safety in practice', *Social Science and Medicine,* 65(3), pp. 599-609.

Brady, A., Malone, A. and Fleming, S. (2009) 'A literature review of the individual and systems factors that contribute to medication errors in nursing practice', *Journal of Nursing Management* 17(6), pp. 679-697. [Online]. doi: 10.1111/j.1365-2834.2009.00995.x. (Accessed: 12 May 2015).

British Association for Sexual Health & HIV (2010) *United Kingdom National Guideline on the Management of Sexually Transmitted Infections and Related Conditions in Children and Young People – 2010.* [Online]. Available at: http://www.bashh.org/documents/2674.pdf (Accessed: 12 May 2015).

British Association for Sexual Health & HIV (2011) *United Kingdom National Guideline on the Management of Adult and Adolescent Complainants of Sexual Assault 2011.* [Online]. Available at: http://www.bashh.org/documents/4450.pdf (Accessed: 12 May 2015).

British Association for Sexual Health & HIV (2015) *2015 UK national guideline for the management of infection with Chlamydia trachomatis.* [Online]. Available at: https://www.bashhguidelines.org/media/1045/chlamydia-2015.pdf (Accessed: 7 November 2016).

British Association for Sexual Health & HIV (2016) *BASHH guidelines*. [Online]. Available at https://www.bashh.org/guidelines (Accessed: 12 December 2016).

British Association for Sexual Health & HIV (2018) *BASHH STIF Competencies.* [Online]. Available at: http://www.bashh.org/BASHH/STIF/STIF_Competencies/BASHH/STIF/STIF_Competency.aspx?hkey=d85718fe-ef35-4770-8d92-09ac1bca2efd (Accessed: 12th February 2017).

Boreham N., Coull, A., Murray, I., Turner-Halliday, F. and Watterson, A. (2013) 'Education programmes preparing independent prescribers in Scotland: An evaluation', *Nurse Education Today,* 33(4), pp. 321-326.

Bowling, A. (2009) Research Methods in Health: Investigating health and health services. 3rd edn. Buckingham: Open University Press.

Bowskill, D., Timmons, S. and James, V. (2013) 'How do nurse prescribers integrate prescribing in practice: case studies in primary and secondary care', *Journal of Clinical Nursing,* 22(13-14), pp. 2077-2086.

Braun, V. and Clarke, V. (2006) 'Using thematic analysis in psychology', *Qualitative Research in Psychology*, 3(2), pp.77-101. [Online]. Available at: http://eprints.uwe.ac.uk/11735/2/thematic_analysis_revised_-_final.pdf (Accessed: 10 April 2016).

Brooks, N., Durning, F., Bell, I. and Charles, J. (2003) 'An evaluation of nurses' record-keeping skills and knowledge of using patient group directions for antibiotics at a walk-in centre', *Journal of Research in Nursing,* 8(6), pp. 440-452.

Brookes, D. and Smith, A. (2007*) Non-Medical Prescribing in Health Care Practice: A toolkit for Students & Practitioners*. Hampshire: Palgrave Macmillan.

Buppert, C. (2011) '10 Habits to Adopt to Avoid Prescribing Errors', *The Journal for Nurse Practitioners,* 7(7), pp. 600-601.

Carberry, M., Connelly, S. and Murphy, J. (2012) 'A prospective audit of a nurse independent prescribing within critical care', *Nursing in Critical Care,* 18(3), pp. 135-141. [Online]. doi: http://dx.doi.org/10.1111/j.1478-5153.2012.00534.x (Accessed: 12 May 2015).

Care Quality Commission (2014) *Nigel's surgery 8: Gillick competency and Fraser guidelines.* [Online]. Available at: http://www.cqc.org.uk/content/gp-mythbuster-8-gillick-competency-and-fraser-guidelines (Accessed: 16 June 2015).

Carey, N. Courtenay, M. and James, J. (2008) 'An evaluation of a diabetes specialist nurse prescriber on the system of delivering medicines to patients with diabetes', *Journal of Clinical Nursing,* 17(12), pp. 1635-1644.

Carey, N., Stenner, K. and Courtenay, M. (2009) 'Prescription writing for diabetes: compliance with good practice', *Nurse Prescribing,* 7(10), pp. 464-468.

Carey, N., Stenner, K. and Courtenay, M. (2014) 'An exploration of how nurse prescribing is being used for patients with respiratory conditions across the east of England', *BMC Health Services Research,* 14(27). [Online]. Available at: https://bmchealthservres.biomedcentral.com/articles/10.1186/1472-6963-14-27 (Accessed: 12 May 2015).

Carryer, J., Gardner, G., Dunn, S. and Gardner, A. (2006) 'The core role of the nurse practitioner: practice, professionalism and clinical leadership', *Journal of Clinical Nursing,* 16, pp. 1818-1825.

Cashin, A., Stasa, H., Dunn, S.V., Pont, L. and Buckley, T. (2014) 'Nurse practitioner prescribing practice in Australia: Confidence in aspects of medication management', *International Journal of Nursing Practice,* 20(1). [Online]. Available at: https://www.ncbi.nlm.nih.gov/pubmed/24580969 (Accessed: 12 May 2015).

Cole, T. and Gillett, K. (2015) 'Are nurse prescribers issuing prescriptions in palliative care?', *Nurse Prescribing*, 13(2), pp. 98-102. [Online]. Available at: https://doi.org/10.12968/npre.2015.13.2.98 (Accessed: 17th November 2017).

Courtenay, M. and Carey, N. (2008) 'Nurse independent prescribing and nurse supplementary prescribing practice: national survey', *Journal of Advanced Nursing,* 61(3), pp. 291- 299.

Courtenay, M. and Gordon, J. (2009) 'A survey of therapy areas in which nurses prescribe and CPD needs', *Nurse Prescribing*, 7(6), pp. 255-262.

Courtenay, M., Carey, N. and Burke, J. (2006) 'Preparing nurses to prescribe medicines for patients with dermatological conditions', *Journal of Advanced Nursing,* 55(6), pp. 698-707.

Courtenay, M., Carey, N. and Burke, J. (2007a) 'Independent extended and supplementary nurse prescribing practice in the UK: A national questionnaire survey', *International Journal of Nursing Studies',* 44(7), pp. 1093-1101.

Courtenay, M., Carey, N. and Burke, J. (2007b) 'Independent extended supplementary nurse prescribers, their prescribing practice and confidence to educate and assess prescribing students', *Nurse Education Today,* 27(7), pp. 739-747.

Courtenay, M., Carey, N. and Stenner, K. (2009a) 'Nurse-prescriber-patient consultations: a case study in dermatology', *Journal of Advanced Nursing,* 65(6), pp. 1207-1217.

Courtenay, M., Carey, N. and Stenner, K. (2012) 'An overview of non medical prescribing across one strategic health authority: a questionnaire survey', *BMC Health Services Research,* 12(138). [Online]. Available at: http://www.biomedcentral.com/1472-6963/12/138 (Accessed: 12 May 2015).

Courtenay, M., Carey, N., Gage, H., Stenner, K. and Williams, P. (2015) 'A comparison of prescribing and non-prescribing nurses in the management of people with diabetes', *Journal of Advance Nursing,* 71(12), pp. 2950-2964.

Courtenay, M., Carey, N., James, J., Hills, M. and Roland, J. (2008) 'An evaluation of a specialist nurse prescriber on diabetes in-patient service delivery', *Journal of Clinical Nursing*, 17(12), pp. 1635-1644.

Courtenay, M. Carey, N., Stenner, K., Lawton, S. and Peters, J. (2011) 'Patients' views of nurse prescribing: Effects on care, concordance and medicine taking', *British Journal of Dermatology,* 164(2), pp. 396-401.

Courtenay, M., Khanfer, R., Harries-Huntly, G., Deslandes, R., Gillespie, D., Hodson, K., Morris, G., Pritchard, A. and Williams, E. (2017a) 'Overview of the uptake and implementation of non-medical prescribing in Wales: a national survey', *BMJ Open,* 7. [Online]. Available at: http://bmjopen.bmj.com/content/7/9/e015313 (Accessed: 24 March 2018).

Courtenay, M., Rowbotham, S., Lim, R., Deslandes, R., Hodson, K., MacLure, K., Peters, S. and Stewart, D. (2017b) 'Antibiotics for acute respiratory tract infections: a mixed-methods study of patient experiences of non-medical prescriber management', *BMJ Open,* 7(3). [Online]. Available at: http://bmjopen.bmj.com/content/7/3/e013515 (Accessed: 24 March 2018).

Courtenay, M., Stenner, K. and Carey, N. (2009b) 'An exploration of the practices of nurse prescribers who care for people with diabetes: a case study', *Journal of Nursing and Healthcare of Chronic Illness*, 1(4), pp. 311-320.

Courtenay, M., Stenner, K. and Carey, N. (2010) 'The views of patients with diabetes about nurse prescribing', *Diabetic Medicine*, 27(9), pp. 1049-1059.

Creedon, R. (2010) 'Nurse prescribing and the need for CPD: an Irish perspective', *Nurse Prescribing,* 8(9), pp.445-448.

Creedon, R., Byrne, S., Kennedy, J. and McCarthy, S. (2015) 'The impact of nurse prescribing on the clinical setting', *British Journal of Nursing*, 24(17), pp. 878-885.

Creedon, R., McCarthy, S. and Byrne, S. (2014) 'To determine the prevalence of potential inappropriate prescribed drugs for elderly patients by nurse prescriber', *International Journal of Pharmacy Practice,* 22(1), pp. 5-6.

Creswell, J.W. (2014) *Research Design Qualitative, Quantitative, and Mixed Methods Approaches.* 4th edn. Los Angeles: Sage Publishing.

Crew, S. (2010) 'Non-medical prescribing in secondary care: an audit*', Nurse Prescribing,* 8(10), pp. 498-502.

Critical Appraisal Skills Programme. (2013). *CASP Checklists.* [Online]. Available at: http://www.casp-uk.net/ (Accessed: 12 Janaury 2015).

Curtis, L. and Burns, A. (2016) *PSSRU: Unit costs of health & social care 2016.* [Online]. Available at http://www.pssru.ac.uk/pub/uc/uc2016/full.pdf?uc=2016-full (Accessed: 18th February 2018).

Cushing, A. and Metcalf, R. (2007) 'Optimizing medicines management: from compliance to concordance', *Therapeutics and Clinical Risk Management*, 3(6), pp. 1047-1058.

Davis, C. (2008) 'Sexual health innovators', *Nursing Standard*, 22(49), pp. 20-21.

Dean, B.S. and Barber, N.D. (1999) 'A validated, reliable method of scoring the severity of medication errors', *American Journal of Health-System Pharmacy,* 56(1), pp.57-62.

Deave, T., Weiss, M. and Salisbury, C. (2003) 'Patient group directions for antibiotic supply in Walk-in Centres: how legal are they?', *British Journal of Community Nursing,* 8(5), pp.209-213.

Department of Health (1999) *Review of prescribing, supply & administration of medicines.* [Online]. Available at: http://webarchive.nationalarchives.gov.uk/20130107105354/http:/www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4077153.pdf (Accessed: 5 March 2014).

Department of Health (2000) *Health Services Circular (HSC 2000/026): Patient Group Directions [England Only].* [Online]. Available at: http://webarchive.nationalarchives.gov.uk/20130107105354/http:/www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4012260.pdf (Accessed: 15 March 2014).

Department of Health (2001) *Sexual Health and HIV strategy.* [Online]. Available at: http://antibiotic-action.com/wp-content/uploads/2011/07/DH-National-strategy-for-sexual-health-and-HIV.pdf (Accessed: 15 March 2014).

Department of Health (2004) *Outline curriculum for training programmes to prepare allied health professionals as supplementary prescribers.* [Online]. Available at: http://webarchive.nationalarchives.gov.uk/20130107105354/http:/www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4089003.pdf (Accessed: 6 March 2014).

Department of Health (2005) Research Governance Framework for Health & Social Care: Second edition, 2005. [Online]. Available at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/139565/dh_4122427.pdf (Accessed: 13 March 2014).

Department of Health (2006a) *Improving Patients' Access to Medicines: A Guide to Implementing Nurse and Pharmacist Independent Prescribing within the NHS in England.* [Online]. Available at http://webarchive.nationalarchives.gov.uk/20130107105354/http:/www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4133747.pdf (Accessed: 4 March 2014).

Department of Health (2006b) *10 High impact changes for genitourinary medicine 48-hour Access*. [Online]. Available at: http://webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_062814.pdf (Accessed: 2 February 2015).

Department of Health (2008) *Genitourinary Medicine 48-hour Access: Getting to target and staying there*. [Online]. Available at: http://www.bashh.org/documents/119/119.pdf (Accessed: 4 March 2014).

Department of Health (2013a) *A* Framework for Sexual Health Improvement in England. [Online]. Available at: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/142592/9287-2900714-TSO-SexualHealthPolicyNW_ACCESSIBLE.pdf (Accessed: 18 April 2017).

Department of Health (2013b) *The health and care system explained.* Department of Health Guidance. [Online]. Available at https://www.gov.uk/government/publications/the-health-and-care-system-explained/the-health-and-care-system-explained (Accessed: 5 March 2014).

Department of Health (2014) Abortion Statistics, England and Wales: 2013. [Online]. Available at: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/319460/Abortion_Statistics__England_and_Wales_2013.pdf (Accessed: 12 April 2015).

Department of Health & Social Care (2018) *Department of Health & Social Care.* [Online]. Available at: https://www.gov.uk/government/organisations (Accessed: 12 March 2018).

Department of Health in Northern Ireland (2018) *About the Department of Health.* [Online]. Available at: https://www.health-ni.gov.uk/about-department-health-social-services-and-public-safety (Accessed: 12 March 2018).

Department of Health, Social Services and Public Safety Northern Ireland (2006) *Improving Patients' Access to Medicines: A Guide to Implementing Nurse and Pharmacist Independent Prescribing within the HPSS in Northern Ireland.* DHSSPSNI. [Online]. Available at: http://www.dhsspsni.gov.uk/patients_access.pdf (Accessed 5 March 2014).

Department of Health, Social Services and Public Safety Northern Ireland (2013) *About the department.* [Online]. Available at: http://www.dhsspsni.gov.uk/index/about_dept.htm (Accessed: 5 March 2014).

Dhalivaal, J. (2011) 'Patients' perspectives on prescribing by nurses in general practice', *Practice Nursing, 22*(1), 41-46.

Dinsdale, P. and Duffin, C. (2004) 'Call for greater prescribing powers in sexual health: sexual health organisations would like more nurses to specialise in STI prevention', *Nursing Standard,* 18(47), pp.6

Dobel-Ober, D. and Brimblecombe, N. (2016) 'National survey of nurse prescribing in mental health services; a follow-up 6 years on', *Journal of Psychiatric and Mental Health Nursing,* 23(6-7), pp. 378-386. [Online]. Available at: https://onlinelibrary.wiley.com/doi/epdf/10.1111/jpm.12329 (Accessed: 15 September 2017).

Dobel-Ober, D., Bradley, E. and Brimblecombe, N. (2013) 'An evaluation of team and individual formularies to support independent prescribing in mental health care', *Journal of Psychiatric and Mental Health Nursing,* 20(1), pp.35-40.

Dornan, T., Ashcroft, D., Heathfield, H., Lewis, P., Miles, J., Taylor, D., Tully, M. and Wass, V. (2009) *An in-depth investigation into causes of prescribing errors by foundation trainees in relation to their medical education. EQUIP study.* [Online]. Available at http://www.gmc-uk.org/FINAL_Report_prevalence_and_causes_of_prescribing_errors.pdf_28935150.pdf (Accessed 12 May 2015).

Drennan, J., Naughton, C., Allen, D., Hyde, A., O'Boyle, K., Felle, P., Treacy, M. and Butler, M. (2011), 'Patients' level of satisfaction and self-reports of intention to comply following consultation with nurses and midwives with prescriptive authority: A cross-sectional survey', *International Journal of Nursing Studies,* 48(7), pp. 808-817.

Drummond, M.F., Sculpher, M.J., Claxton, K., Stoddart, G.L. and Torrance, G.W. (2015) *Methods for the Economic Evaluation of Health Care Programmes*. 4th edn. Oxford: University Press.

Earle, E., Taylor, J., Peet, M. and Grant, G. (2011) 'Nurse prescribing in specialist mental health (Part 1): the views and experiences of practising and non-practising nurse prescribers and service users', *Journal of Psychiatric & Mental Health Nursing,* 18(3), pp. 189-197. [Online]. Available at: doi: 10.1111/j.1365-2850.2010.01672.x (Accessed: 12 May 2015).

Endacott, R (2008) 'Clinical research 4: qualitative data collection and analysis', *International Emergency Nursing,* 16(1), pp. 48-52.

Estcourt, C., Tyler, C., Nelson, M. and Bickford, J. (2011) 'Challenges facing nurse-led STI care and sexual reproductive health: education, education, education!' *Sexually Transmitted Infections,* 87(6), pp.453.

Evans, D.T. (2013) 'Promoting sexual health and wellbeing: the role of the nurse', *Nursing Standard,* 28(10), pp.53-57.

Faculty of Sexual and Reproductive Health (2016a) *Standards & guidance.* [Online]. Available at: https://www.fsrh.org/standards-and-guidance/ (Accessed: 12 December 2016).

Faculty of Sexual and Reproductive Health (2016b) *Education & Training.* [Online]. Available at: https://www.fsrh.org/education-and-training/ (Accessed: 15 June 2016).

Family Planning Association (2012) *What does the Health and Social Care Bill mean for sexual health services in England?* [Online]. Available at: http://www.fpa.org.uk/sites/default/files/health-and-social-care-bill-and-sexual-health-services-march-2012.pdf (Accessed: 12 May 2015)

Field, A. (2009) *Discovering statistics using SPSS.* 3rd edn. London: Sage.

European Union (2016) *General Data Protection Regulation (GDPR) (EU) 2016/679.*

Gerard, K., Tinelli, M., Latter, S., Smith, A. and Blenkinsopp, A. (2014) 'Patients' valuation of the prescribing nurse in primary care: a discrete choice experiment', *Health Expectations,* 18(6), pp.2223-2235.

Gerrish, K. and Lacey, A. (2010) *The Research Process in Nursing*. 6th edn. Oxford: Blackwell Publishing Ltd.

Gielen, S.C., Dekker, J., Franke, A.L., Mistiaen, P. and Kroezen, M. (2014) 'The effects of nurse prescribing: A systematic review', *International Journal of Nursing Studies* 51(7), pp. 1048-1061.

Goryakin, Y., Griffiths, P. and Maben, J. (2011) 'Economic evaluation of nurse staffing and nurse substitution in health care: A scoping review', *International Journal of Nursing Studies*, 48(4), pp. 501-512.

Gray, J., Afzali, H.H.A., Beilby, J., Holton, C., Banham, D. and Karnon, J. (2014) 'Practice nurse involvement in primary care depression management: an observational cost-effectiveness analysis', *BMC Family Practice,* 15(10). [Online]. Available at: doi: 10.1186/1471-2296-15-10. (Accessed 12 March 2015).

Great Britain. *Abortion Act 1967: Elizabeth II. Chapter 87.* London: The Stationary Office.

Great Britain. *Data Protection Act 1998: Elizabeth II. Chapter 29.* London: The Stationary Office.

Great Britain. *Family Law Reform Act 1969: Elizabeth II. Chapter 46.* London: The Stationary Office.

Great Britain. *Health and Social Care Act 2001: Elizabeth II. Chapter 15.* London: The Stationary Office.

Great Britain. *Health and Social Care Act 2012: Elizabeth II. Chapter 7.* London: The Stationary Office.

Great Britain. *Health and Social Care (Safety and Quality) Act 2015: Elizabeth II. Chapter 28.* London: The Stationary Office.

Great Britain. *Medicinal Products: Prescription by Nurses etc. Act 1992: Elizabeth II. Chapter 28.* London: The Stationary Office.

Great Britain. *Medicines Act 1968: Elizabeth II. Chapter* 67. London: The Stationary Office.

Great Britain. *Misuse of Drugs Act 1971: Elizabeth II. Chapter 38.* London: The Stationary Office.

Great Britain. The National Health Service (*Venereal Diseases) Regulations 1974: Elizabeth II. Chapter 29 XXI.* London: The Stationary Office.

Great Britain. *Sexual Offences Act 2003: Elizabeth II. Chapter 42.* London: The Stationary Office.

Green, A., Westwood, O., Smith, Peniston-Bird, F. and Holloway, D. (2009) 'Provision of continued professional development for non-medical prescribers within a South of England Strategic Health Authority: a report on a training needs analysis', *Journal of Nursing Management,* 17(5), pp. 603-614.

Greveson, K. (2009) 'An audit of independent non-medical prescribing in inflammatory bowel disease', *Gastrointestinal Nursing,* 7(10), pp. 23-27.

Gumber, R., Khoosal, D. and Gajebasia, N. (2012) 'Non-medical prescribing: audit, practice and views', *Journal of Psychiatric and Mental Health Nursing,* 19(6), pp.475-481.

Hanlon, J.T., Schmader, K.E., Samsa, G.P., Weinberger, M., Uttech, K.M., Lewis, I.K., Cohen, H.J. and Feussner, J.R. (1992) 'A method for assessing drug therapy appropriateness', *Journal of Clinical Epidemiology,* 45(10), pp. 1045-1051.

Handy, P. (2002) 'Nurse-directed services in genitourinary medicine', *Nursing Standard,* 17(11), pp.33-38.

Health & Social Care Information Centre (2015) *Prescription Cost Analysis, England – 2014*. [Online]. Available at: http://www.hscic.gov.uk/article/2021/Website-Search?productid=17711&q=prescription+cost+analysis&sort=Relevance&size=10&page=1&area=both#top (Accessed: 16 September 2015).

Health Protection Agency (2011) *Health Protection Report* 5(24). [Online]. Available at http://www.hpa.org.uk/hpr/archives/2011/hpr2411.pdf(Accessed: 8 July 2014)

Horne, R., Hankins, M. and Jenkins, R. (2001) 'The satisfaction with Information about Medicines Scale (SIMS): a tool for audit and research', *International Journal for Quality in Health Care*, 10(3), pp. 135-140.

Hobson, R., Scott, J. and Sutton, J. (2010) 'Pharmacists and nurses as independent prescribers: Exploring the patient's perspective', *Family Practice,* 27(1), pp. 110-120.

Home Office UK (2012) *Nurse and pharmacist independent prescribing, 'mixing of medicines', possession authorities under patient group directions and personal exemption provisions for Schedule 4 Part II drugs.* Home Office UK circular 009/2012. [Online]. Available at https://www.gov.uk/government/publications/nurse-and-pharmacist-independent-prescribing-mixing-of-medicines-possession-authorities-under-patient-group-directions-and-personal-exemption-provisions-for-schedule-4-part-ii-drugs (Accessed: 5 March 2014).

Hopia, H., Karhunen, A. and Heikkila (2016) 'Growth of nurse prescribing competence: facilitators and barriers during education', *Journal of Clinical Nursing*, 26(19-20), pp. 3164-3173.

Hyde, A., Coughlan, B., Naughton, C., Hegarty, J., Savage, E., Grehan, J. ,Kavanagh, E., Moughty, A. and Drennan, J. (2016) 'Nurses', physicians and radiographers perceptions of the safety of a nurse prescribing of ionising radiation initiative: A cross-sectional survey', *International Journal of Nursing Studies*, 58, pp. 21-30. [Online]. Available at: doi: 10.1016/j.ijnurstu.2016.01.004. (Accessed: 31 March 2018).

Institute of Psychosexual Medicine (2018) *Examinations.* [Online]. Available at https://www.ipm.org.uk/60/examinations (Accessed: 6 September 2018).

Jones, K. (2009) 'Developing a prescribing role for acute care nurses', *Nursing Management,* 16(7), pp.24-28.

Jones, K., Edwards, M. and While, A. (2010) 'Nurse prescribing roles in acute care: an evaluative case study', *Journal of Advanced Nursing*, 67(1), pp.117-126.

Kaufmann, C.P., Tremp, R., Hersberger, K.E. and Lampert, M.L. (2014) 'Inappropriate prescribing: a systematic overview of published assessment tools', *European Journal of Clinical Pharmacology,* 70(1), pp. 1-11. [Online]. Available at: doi: 10.1007/s00228-013-1575-8. (Accessed: 12 May 2015).

Keefe, A. (2008) 'Development of nurse-led clinics in genitourinary medicine', *Nurse Prescribing,* 6(6), pp. 246-250.

Kroezen, M., de Veer, A., Francke, A., Groenewegen, P. and van Dijk, L. (2014) 'Changes in nurses' views and practices concerning nurse prescribing between 2006 and 2012: results from two national surveys', *Journal of Advanced Nursing.* 70(11), pp. 2550-2561.

Kroezen, M., Francke, A.L., Groenewegen, P.P. and van Dijk, L., (2012) 'Nurse prescribing of medicines in Western Europe and Anglo-Saxon countries: A survey of forces, conditions, and jurisdictional control', *International Journal of Nursing Studies,* 49(8), pp. 1002-1012.

Kroezen, M., van Dijk, L., Groenewegen, P.P. and Francke, A.L. (2011) 'Nurse prescribing of medicines in Western European and Anglo-Saxon countries: a systematic review of the literature', *BMC Health Services Research*, 11(127). [Online]. Available at http://www.biomedcentral.com/content/pdf/1472-6963-11-127.pdf (Accessed: 12 May 2015).

Latter, S. (2011) 'Qualitative study: consultations between nurse prescribers and patients with diabetes in primary care: a qualitative study of patient views', *Evidence-Based Nursing,* 14(4), pp. 124-125.

Latter, S. and Courtenay, M. (2004) 'Effectiveness of nurse prescribing: a review of the literature', *Journal of Clinical Nursing,* 13(1), pp. 26-32.

Latter, S., Blenkinsopp, A., Smith, A., Chapman, S., Tinelli, M., Gerard, K., Little, P., Celino, N., Granby, T., Nicholls, P. and Dorer, G. (2010) *Evaluation of nurse and pharmacist independent prescribing.* [Online]. Available at: https://eprints.soton.ac.uk/184777/3/ENPIPfullreport.pdf (Accessed: 12 May 2015).

Latter, S., Maben, J. and Myall, M. (2007a) 'Evaluating prescribing competencies and standards used in nurse independent prescribers' prescribing consultations: an observation study of practice in England', *Journal of Research in Nursing,* 12(1), pp. 7-28.

Latter, S., Maben, J., Myall, M. and Young, A. (2007b) 'Evaluating the clinical appropriateness of nurses' prescribing practice: method development and findings from an expert panel analysis', *Quality and Safety in Healthcare,* 16(6), pp. 415–421.

Latter, S., Maben, J., Myall, M. and Young, A. (2007c) 'Evaluating nurse prescribers' education and continuing professional development for independent prescribing practice: Findings from a national survey in England', *Nurse Education Today,* 27(7), pp. 685-696.

Latter, S., Maben, J., Myall, M. and Young, A. (2007d) 'Perceptions and practice of concordance in nurses' prescribing consultations: Findings from a national questionnaire survey and case studies of practice in England', *International Journal of Nursing Studies,* 44(1), pp.9-18.

Latter, S., Maben, J., Myall, M., Young, A., Courtenay, M. and Dunn, N. (2005) *An evaluation of extended formulary extended independent nurse prescribing. Final Report, School of Nursing & Midwifery, University of Southampton.* [Online]. Available at: https://eprints.soton.ac.uk/17584/ (Accessed: 12 May 2015).

Latter, S., Sibley, A. and Skinner, T. (2010) 'The impact of an intervention for nurse prescribers on consultations to promote patient medicine-taking in diabetes: a mixed methods study', *International Journal of Nursing Studies,* 47(9), pp. 1126-1138.

Latter, S., Smith, A., Blenkinsopp, A., Nicholls, P., Little, P. and Chapman, S. (2012) 'Are nurse and pharmacist independent prescribers making clinically appropriate prescribing decisions? An analysis of consultations', *Journal of Health Services Research and Policy,* 17(3), pp. 149-156.

Leufer, T. and Cleary-Holdforth (2013) 'Let's do no harm: Medication errors in nursing: Part 1', *Nurse Education in Practice,* 13(3), pp. 213-216.

Lim, A.G., North, N. and Shaw, J. (2017) 'Navigating professional and prescribing boundaries: Implementing nurse prescribing in New Zealand', *Nurse Education in Practice*, 27. [Online]. Available at: https://www.ncbi.nlm.nih.gov/pubmed/28802979 (Accessed: 31 March 2018).

Ling, D.L., Lyu, C.M., Liu, H., Xiao, X. and Yu, H.J. (2018) 'The necessity and possibility of implementation of nurse prescribing in China: An international perspective', *International Journal of Nursing Sciences,* 5(1), pp. 72-80.

Lipetz, C., Phillips, C. and Fleming, C. (2009) 'Actual cost of providing long-acting reversible contraception: a study of Implanon(R) cost', *Journal of Family Planning and Reproductive Health Care,* 35(2), pp. 75-79.

London Councils (2017) *Sexual Health London*. [Online]. Available at: https://www.londoncouncils.gov.uk/our-key-themes/health-and-adult-services/public-health/sexual-health-0/london-sexual-health (Accessed: 12 February 2018).

MacLure, K., George, J., Diack, L., Bond, C., Cunningham, S. and Stewart, D. (2013) 'Views of the Scottish general public on non-medical prescribing', *International Journal of Clinical Pharmacy, 35*(5), pp. 704-710.

Mauskopf, J.A., Paul, P.E., Grant, D.M. and Stergachis, A. (1998) 'The role of cost-consequence analysis in healthcare decision-making', *Pharmacoeconomics,* 13(3), pp. 277-288.

McCann, T. and Clark, E. (2008) 'Attitudes of patients towards mental health nurse prescribing of antipsychotic agents', *International Journal of Nursing Practice,* 14(2), pp. 115-121.

McClellan, C.M., Cramp, F., Powell, J. and Benger, J.R. (2013) 'A randomised trial comparing the cost effectiveness of different emergency department healthcare professionals in soft tissue injury management', *BMJ Open*, 3(1). [Online]. Available at: http://bmjopen.bmj.com/content/3/1/e001116 (Accessed: 12 May 2015).

Meakin, R. and Weinman (2002) 'The medical interview satisfaction scale (MISS-21) adapted for British General Practice', *Family Practice,* 19(3), pp. 257-263.

Medical Foundation for HIV & Sexual Health (2008) *Progress and priorities – working together for high quality sexual health. Review of the National Strategy for Sexual Health and HIV.* [Online]. Available at: http://www.medfash.org.uk/uploads/files/p17abl1iai1e961d438j2pjl1rp7p.pdf (Accessed: 5 March 2015).

Medical Foundation for HIV & Sexual Health (2014) *Standards for the management of sexually transmitted infections (STIs).* [Online]. Available at: http://www.medfash.org.uk/uploads/files/p18dtqli8116261rv19i61rh9n2k4.pdf (Accessed: 5 March 2015)

Medicines and Healthcare products Regulatory Agency (2008) *Medicines and medical devices regulations: what you need to know.* [Online]. Available at: http://www.mhra.gov.uk/home/groups/comms-ic/documents/websiteresources/con2031677.pdf (Accessed: 18 March 2014).

Medicines and Healthcare products Regulatory Agency (2009) *Medical and non-medical prescribing: mixing medicines in clinical practice.* [Online]. Available at: https://www.gov.uk/drug-safety-update/medical-and-non-medical-prescribing-mixing-medicines-in-clinical-practice (Accessed: 5 March 2014).

Medicines and Healthcare products Regulatory Agency (2011) *How we regulate medicines.* [Online]. Available at: http://www.mhra.gov.uk/Howweregulate/Medicines/index.htm (Accessed: 18 March 2014).

Medicines and Healthcare products Regulatory Agency (2013) *The human medicines regulations 2012.* [Online]. Available at: http://www.mhra.gov.uk/Howweregulate/Medicines/Overviewofmedicineslegislationandguidance/TheHumanMedicinesRegulations2012/ (Accessed: 08 March 2014).

Medicines and Healthcare products Regulatory Agency (2014) *Patient Safety Alert Stage Three: Directive. Improving medication error incident reporting and learning.* [Online]. Available at: http://www.england.nhs.uk/wp-content/uploads/2014/03/psa-sup-info-med-error.pdf (Accessed: 16 November 2016).

Medication Protection Society (2016) *Why patient decide to take action against doctors.* [Online]. Available at: https://www.medicalprotection.org/uk/for-members/general-practice/gp-articles/gp-articles/why-patients-decide-to-take-action-against-doctors (Accessed: 11 November 2017).

Microsoft Office (2013) *Microsoft Access.* [Computer program].

Microsoft Office (2013) *Microsoft Excel.* [Computer program].

Miles, K., Penny, N., Rees, L. and MacDougal, H. (2001) 'Patient group directions in nurse-led sexual health clinics', *Nursing Standard,* 16(7), pp. 33-34.

Milligan, F. (2012) 'Self-reflection assessment on prescribing and patient satisfaction', *Nurse Prescribing*, 10(6), pp. 306-308.

Monyatsi, G., Mullan, P.C., Phelps, B.R., Tolle, M.A., Machine, E.M., Gennari, F.F., Makosky, J. and Anabwani, G.M. (2012) 'HIV management by nurse prescribers compared with doctors at a paediatric centre in Gaborone, Botswana', *South African Medical Journal,*102(1), pp. 34-37.

Moule, P. and Goodman, M. (2009) *Nursing Research: An introduction.* London: Sage.

Natan, M., Kabaha, A., Jackob, N., Atallah, R. and Sharon, I. (2013) 'The attitudes of patients with chronic conditions towards nurse prescribing medications', *International Nursing Review,* 60(4), pp. 469-476.

National Health Service Digital (2017) *Prescribing Costs in Hospitals and the Community, England 2016/17.* [Online]. Available at: https://digital.nhs.uk/catalogue/PUB30152 (Accessed: 4 February 2018).

National Health Service Employers (2017) *NHS Terms and Conditions of Service Handbook* [Online]. Available at: http://www.nhsemployers.org/employershandbook/afc_tc_of_service_handbook_fb.pdf (Accessed: 14 March 2016).

National Health Service England (2013) *News: 67 new clinical commissioning groups given green light to take control of NHS budgets.* [Online]. Available at: http://www.england.nhs.uk/2013/01/23/wave2-auth/ (Accessed: 05 March 2014).

National Health Service Health Research Authority (2016) *Planning & improving research.* [Online]. Available at: https://www.hra.nhs.uk/planning-and-improving-research/ (Accessed: 15 November 2016).

National Health Service Improvement (2017) *National quarterly data on patient safety incident reported: March 2017.* [Online]. Available at: https://improvement.nhs.uk/resources/national-quarterly-data-patient-safety-incident-reports-march-2017/ (Accessed: 12 September 2017).

National Institute for Health and Care Excellence (2013) *Medicines Practical guidelines: patient group directions.* [Online]. Available at http://www.nice.org.uk/media/2AF/07/MPG2Guidance.pdf (Accessed: 13 December 2016).

National Institute of Clinical Excellence (2014a) 'BNF: Prescribing for the elderly' [Online] Available at http://www.evidence.nhs.uk/formulary/bnf/current/guidance-on-prescribing/prescribing-for-the-elderly (Accessed: 8 July 2014)

National Institute for Health and Care Excellence (2014b) Medicines and prescribing. [Online]. Available at: https://www.nice.org.uk/about/nice-communities/medicines-and-prescribing (Accessed: 15 April 2014).

National Patient Safety Agency (2009) *Safety in doses.* [Online]. Available at: http://www.nrls.npsa.nhs.uk/resources/patient-safety-topics/medication-safety/?entryid45=61625&p=2 (Accessed: 16 March 2014).

National Patient Safety Agency (2012) *Medication safety.* [Online]. Available at: http://www.nrls.npsa.nhs.uk/resources/patient-safety-topics/medication-safety/ (Accessed: 15 April 2014).

National Prescribing Centre (National Institute for Health and Care Excellence; 2012) *A single competency framework for all prescribers.* [Online]. Available at:

https://www.associationforprescribers.org.uk/images/Single_Competency_Framework.pdf (Accessed: 15 April 2014).

Naughton, C., Drennan, J., Hyde, A., Allen, D., O'Boyle, K., Felle, P. and Butler, M. (2013) 'An evaluation of the appropriateness and safety of nurse and midwife prescribing in Ireland', *Journal of Advanced Nursing,* 69(7), pp. 1478-1488.

Ness, V., Malcolm, W., McGivern, G. and Reilly, J. (2015) 'Growth in nurse prescribing of antibiotics: the Scottish experience 2007-13', *Journal of Antimicrobial Chemotherapy,* 70(12), pp. 3384-3389.

Noblet, T., Marriott, J., Graham-Clarke, E., Shirley, D. and Rushton, A. (2018) 'Clinical and cost-effectiveness of non-medical prescribing: A systematic review of randomised controlled trials', *PLOS ONE.* [Online]. Available at: https://doi.org/10.1371/journal.pone.0193286. (Accessed: 31 March 2018).

Norman, I., Coster, S., McCrone, P., Sibley, A. and Whittlesea, C. (2010) 'A comparison of the clinical effectiveness and costs of mental health nurse supplementary prescribing and independent medical prescribing: a post-test control group study', *BMC Health Services Research,* 10(4). [Online]. Available at: doi: 10.1186/1472-6963-10-4. (Accessed: 12 May 2015).

Nursing & Midwifery Council (NMC) (2005) *Statistical analysis of the register 1 April 2004 to 31 March 2005* [Online]. Available at: http://www.nmc-uk.org/Documents/Statistical%20analysis%20of%20the%20register/NMC%20Statistical%20analysis%20of%20the%20register%202004%202005.pdf (Accessed: 11 March 2014).

Nursing & Midwifery Council (2006) *Standards proficiency nurse and midwife prescribers*. [Online]. Available at: http://www.nmc-uk.org/Documents/NMC-Publications/NMC-Standards-proficiency-nurse-and-midwife-prescribers.pdf (Accessed: 8 March 2015).

Nursing & Midwifery Council (2008) *The code.* [Online]. Available at: http://www.nmc-uk.org/documents/standards/the-code-A4-20100406.pdf (Accessed: 12 March 2014).

Nursing & Midwifery Council (2010a) *What we do*. [Online]. Available at: http://www.nmc-uk.org/patients-public/What-the-NMC-does/ (Accessed: 12 March 2014).

Nursing & Midwifery Council (2010b) *Standards for medicines management*. [Online]. Available at: http://www.nmc-uk.org/Documents/NMC-Publications/NMC-Standards-for-medicines-management.pdf (Accessed: 12 March 2014).

Nursing & Midwifery Council (2010c) *Nurse and midwife independent prescribing of unlicensed medicines.* [Online]. Available at: http://www.nmc-uk.org/Documents/Circulars/2010circulars/NMCcircular04_2010.pdf (Accessed: 8 March 2014).

Nursing & Midwifery Council (2012) *Amendments to Home Office Misuse of Drugs Regulations 2001*. [Online]. Available at: http://www.nmc-uk.org/media/Latest-news/Amendments-to-Home-Office-Misuse-of-Drugs-Regulations-2001/ (Accessed: 9 March 2014).

Nursing & Midwifery Council (2014) *Consultation on revalidation and the revised Code*. [Online]. Available at: http://www.nmc-uk.org/Get-involved/Consultations/Consultation-on-revalidation-and-the-revised-Code/ (Accessed: 12 March 2014).

Nursing & Midwifery Council (2015) *The Code: Professional standards of practice and behaviours for nurses and midwives.* [Online]. Available at: *http://www.nmc-uk.org/Documents/NMC-Publications/revised-new-NMC-Code.pdf* (Accessed: 12 September 2017).

Nursing & Midwifery Council (2015) *Standards of proficiency for nurse and midwife prescribers.* [Online]. Available at: https://www.nmc.org.uk/globalassets/sitedocuments/standards/nmc-standards-proficiency-nurse-and-midwife-prescribers.pdf (Accessed: 12 September 2017).

Nuttall, S., Dobson, C. and Mills, R. (2008) 'Evaluation of the antibiotic prescribing of nurse practitioners trained to prescribe in primary care', *Primary Health Care Research and Development*, 9(3), pp. 199-204.

Nvivo Version 10 (2012) *Nvivo*. [Computer program].

Parahoo, K. (2006) *Nursing Research: Principles, Process and Issues.* 2nd edn. Basingstoke: Palgrave Mac Millian.

Petty, D.R. (2012) 'Ten tips for safer prescribing by non-medical prescribers', *British Journal of Cardiac Nursing,* 8(1). [Online]. Available at: doi.org/10.12968/bjca.2013.8.1.24 (Accessed: 12 May 2015).

Pontin, D. and Jones, S. (2007) 'Children's nurses and nurse prescribing: a case study identifying issues for developing training programmes in the UK', *Journal of Clinical Nursing*, 16(3), pp.540-548.

Price, O., Baker, J., Paton, C. and Barnes, T. (2012) 'Patient Group Directions: a safe and effective practice?', *British Journal of Nursing,* 21(1), pp. 26-31.

Public Health England STI rates (2017a) *Sexually transmitted infections (STIs): annual data tables.* [Online]. Available at: https://www.gov.uk/government/statistics/sexually-transmitted-infections-stis-annual-data-tables (Accessed: 12 February 2018).

Public Health England (2017b) *Official Statistics Pregnancy and birth profiles: 2017 update.* [Online]. Available at: https://www.google.co.uk/search?ei=fDbCWpnmIo7VkwXl5YroBA&q=uk+teenage+pregnancy+statistics+2017&oq=uk+teenage+pregnancy+statistics+2&gs_l=psy-ab.1.1.0l2j0i22i30k1l8.2532.2943.0.5344.3.3.0.0.0.0.68.190.3.3.0....0...1c.1.64.psy-ab..0.3.189....0.Xe5DcuvFA1I (Accessed: 12 February 2018).

Raebel, M.A., Charles, J., Dugan, J., Carroll, N.M., Korner, E.J., Brand, D.W. and Magid, D.J. (2007) 'Randomized trial to improve prescribing safety in ambulatory elderly patients', *Journal of the American Geriatrics Society*, 55(7), pp. 977–985.

Reed, P.G. (1997) 'Nursing: The ontology of the discipline', *Nursing Science Quarterly,* 10(2), pp.76-79.

Riley, R., Weiss, M.C., Platt, J., Taylor, G., Horrocks, S. and Taylor, A. (2013) 'A comparison of GP, pharmacist and nurse prescriber responses to patients' emotional cues and concerns in primary care consultations', *Patient Education and Counselling,* 91 (1), pp. 65-71.

Ritchie, J., Lewis, J., McNaughton Nicholls, C. and Ormston, R. (2013) *Qualitative Research Practice: A guide for social science students & researchers.* 2nd edn. London: Sage.

Roberts, C. (2005) 'Scope of practice', *Nursing Management*, 12(8), pp.30-31.

Robertson, K.E. (1996) 'Process for preventing or identifying and resolving problems in drug therapy', *American Journal of Health-System Pharmacy*, 53(6), pp. 639–650.

Robinson, A.J. and Rogstad, K. (2003) 'Moderization in GUM/HIV services: what does it mean?', *International Journal of STD & AIDS*, 14(2), pp. 89-98.

Robinson, G. (2009) 'Integrated sexual health: a better way of working?', *Journal of Family Planning and Reproductive Health Care,* 35(4), pp.249-250.

Robson, W. (2013) 'Prescribing errors: taking the human factor into account', *Nurse Prescribing,* 11(9), pp. 455-458.

Ross, J.D. (2015) 'Mental health nurse prescribing: the emerging impact', Journal of psychiatric and Mental Health Nursing, 22(7), pp. 529-542.

Ross, J., Clarke, A. and Kettles, A. (2014) 'Mental health nurse prescribing: using a constructivist approach to investigate the nurse-patient relationship', *Journal of Psychiatric and Mental Health Nursing, 21*(1), pp. 1-10.

Royal College of Nursing (2012) *RCN Fact sheet nurse prescribing in the UK*. [Online]. Available at http://www.rcn.org.uk/__data/assets/pdf_file/0008/443627/Nurse_Prescribing_in_the_UK_-_RCN_Factsheet.pdf (Accessed: 12 March 2014).

Royal College of Nursing (2012b) *RCN Competencies: Advanced nurse practitioners: An RCN guide to advanced nursing practice, advanced nurse practitioners and programme accreditation.* [Online]. http://www.rcn.org.uk/__data/assets/pdf_file/0003/146478/003207.pdf (Accessed: 16 June 2014).

Royal Pharmaceutical Society (2016) *A competency Framework for all Prescribers.* [Online]. Available at: https://www.rpharms.com/Portals/0/RPS%20document%20library/Open%20access/Professional%20standards/Prescribing%20competency%20framework/prescribing-competency-framework.pdf (Accessed: 12 February 2017).

Schirle, L. and McCabe, B.E. (2016) 'State variation in opioid and benzodiazepine prescriptions between independent and nonindependent advanced practice registered nurse prescribing states', *Nursing Outlook,* 64(1), pp.86-93.

Schultz, P.R. and Meleis, A.I. (1988) 'Nursing Epistemology: Traditions, Insights, Questions', *Journal of Nursing Scholarship,* 20(4), pp. 217-221.

Scottish Government Health and Social Care Directorate (2013) *Structure of NHS Scotland.* [Online]. Available at: http://www.scotland.gov.uk/Topics/Health/About/NHS-Scotland (Accessed: 5 March 2014).

Seden, K., Kirkham, J., Kennedy, T., Lloyd, M., James, S., McManus, A., Ritchings, A., Simpson, J., Thorton, D., Gill, A., Coleman, C., Thorpe, B. and Khoo, S. (2013) 'Cross-sectional study of prescribing errors in patient admitted to nine hospitals across North West England', *British Medical Journal.* 3(1). [Online]. Available at: doi:10.1136/bmjopen-2012-002036 (Accessed: 12 May 2015).

SH:24 (2017) *About SH:24.* [Online]. Available at: https://sh24.org.uk/about-sh24 (Accessed: 20 March 2018).

Sibley, A., Latter, S., Richard, C., Lussier, M., Roberge, D. and Skinner, T. (2011) 'Medication discussion between nurse prescribers and people with diabetes: an analysis of content and participation using MEDICODE', *Journal of Advanced Nursing,* 67(11), pp. 2323-2336. [Online]. Available at: doi: http://dx.doi.org/10.1111/j.1365-2648.2011.05686.x (Accessed: 12 May 2015).

Smith, A., Latter, S. and Blenkinsopp, A. (2014) 'Safety and quality of nurse independent prescribing: a national study of experiences of education, continuing professional development clinical governance', *Journal of Advanced Nursing,* 70(11), pp. 2506-2517. [Online]. Available at: doi: http://dx.doi.org/10.1111/jan.12392 (Accessed: 12 May 2015).

Statistical Package for the Social Sciences Version 24.0 (2016) *SPSS Statistics 24*. [Computer program].

Stenner, K. and Courtenay, M. (2008) 'Benefits of nurse prescribing for patients in pain: nurses' views', *Journal of Advanced Nursing*, 63(1), pp. 27-35.

Stenner, K., Courtenay, M. and Carey, N. (2011) 'Consultations between nurse prescribers and patients with diabetes in primary care: a qualitative study of patient views', *International Journal of Nursing Studies,* 48(1), pp.37-46.

Stewart, D., MacLure, K., Paudyal, V., Hughes, C., Courtenay, M. and McLay, J. (2013) 'Non-medical prescribers and pharmacovigilance: Participation, competence and future needs', *International Journal of Clinical Pharmacy,* 35(2), pp. 268-274.

Sutton, M., Garfield-Birkbeck, S., Martin, G., Meacock, R., Morris, S., Sculpher, M., Street, A., Watson, S.I. and Lilford, R.J. (2018) *Economic analysis of service and delivery interventions in health care*. [Online]. Available at: https://www.ncbi.nlm.nih.gov/books/NBK481909/ (Accessed: 1 March 2018).

The Cumberlege, J. (1986) *Neighbourhood nursing: a focus for care: report of the Community Nursing Review.* [Online]. Available at: https://capitadiscovery.co.uk/bcu/items/469582. (Accessed: 10 March 2014).

The Human Medicines Regulations 2012 (SI 2012/1916). [Online]. Available at: http://www.legislation.gov.uk/uksi/2012/1916/pdfs/uksi_20121916_en.pdf (Accessed: 27 February 2014)

The Misuse of Drugs (Amendment No.2) (England, Wales and Scotland) Regulations 2012 (SI 2012/973). [Online]. Available at: http://www.legislation.gov.uk/uksi/2012/973/pdfs/uksi_20120973_en.pdf (Accessed: 10 March 2014).

Tinelli, M., Blenkinsopp, A., Latter, S., Smith, A. and Chapman, S. (2013) 'Survey of patients' experiences and perceptions of care provided by nurse and pharmacist independent prescribers in primary care', *Health Expectations,* 18(5), pp. 1241-1255.

Tufford, L. and Newman, P. (2010) 'Bracketing in Qualitative Research', *Qualitative Social Work,* 11(1), pp80-96.

UK Government (2018) *Policy Brexit.* [Online]. Available at: https://www.gov.uk/government/policies/brexit (Accessed: 30 March 2018).

Velo, G.P. and Minuz, P. (2009) 'Medication errors: prescribing faults and prescription errors', *British Journal of Clinical Pharmacology,* 67(6), pp. 624-628.

Wagle, S. (2011) 'Using the British National Formulary: best practice for nurse prescribers', *Nursing Standard,* 26(3), pp. 43-48.

Wainwright, J. and Canning, D. (2008) 'Non-medical prescriber audit: evidence of CPD', *Nurse Prescribing,* 6(1), pp. 21-25.

Walsh, M. (2004) 'In the name of independence', *Nursing Standard,* 18(41), pp.27

Wat, D. (2014) 'Reducing admissions with patient group directions', *Nursing Times*, 110(16), pp. 18-20.

Weiss, M.C., Platt, J., Riley, R., Taylor, G., Horrocks, S. and Taylor, A. (2013) 'Solicitations in GP, nurse and pharmacist prescriber consultations: An observational study', *Family Practice,* 30(6), pp. 712-718.

Welsh Government(2018) *Health and Social Services.* [Online]. Available at: http://gov.wales/topics/health/?lang=en (Accessed: 30 March 2018).

Welsh Government Health & Social Services (2011) *Health services.* [Online]. Available at http://wales.gov.uk/topics/health/nhswales/healthservice/?lang=en (Accessed: 5 March 2014).

Welsh Government Public Health (2013) *Health and social services.* [Online]. Available at: http://wales.gov.uk/about/civilservice/directorates/hsscdirectorate/phhp/?lang=en (Accessed: 5 March 2014).

West, L., Cordina, M. and Cunningham, S. (2012) 'Clinical pharmacist evaluation of medication inappropriateness in the emergency department of a teaching hospital in Malta', *Pharmacy Practice*, 10(4), pp.181-187.

Weston, R.L., Hopwood, B., Harding, J., Sizmur, S. and Ross, J.D.C. (2010) 'Development of a validated patient satisfaction survey for sexual health clinic attendees', *International Journal of STD & AIDS,* 21(8), pp. 584-590.

Wilkinson, J., Carryer, J. and Adams, J. (2014) 'Evaluation of a diabetes nurse specialist prescribing project', *Journal of Clinical Nursing, 23*(15-16), pp. 2355-2366.

Williams, A. and Knox, S. (2011) 'Use of patient group directions in an emergency care centre', *Emergency Nurse,* 18(10), pp. 33-37.

Willis (2015) *Raising the Bar. Shape of Caring: A Review of the future Education and Training of Registered Nurses and Care Assistants.* [Online]. Available at: https://hee.nhs.uk/sites/default/files/documents/2348-Shape-of-caring-review-FINAL.pdf (Accessed: 18 September 2018).

Wilson, M., Gerber, K., Mahoney, S. and Odell, M. (2012) 'An audit of independent nurse prescribing in a critical care outreach team', *Nursing in Critical Care,* 17(2), pp. 83-89.

Wilson, E. (2014) 'Nurse-led management of contraceptive services', *Nursing Standard,* 28(43), pp.45-49.

Woodley (2009) *Osborn's Concise Law Dictionary.* 11th edn. London: Thomson Reuters (Legal) Limited.

World Health Organisation (2017) *Antibiotic resistance fact sheet*. [Online]. Available at: http://www.who.int/mediacentre/factsheets/fs194/en/ (Accessed: 12 September 2017).

World Health Organisation (2006) Sexual health definition. [Online]. Available at: http://www.who.int/reproductivehealth/topics/sexual_health/sh_definitions/en/ (Accessed: 12 February 2014)

World Medical Association (1996) *WMA Declaration of Helsinki – ethical principles for medical research involving human subjects.* [Online]. Available at: https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/ (Accessed: 13 February 2014).

Appendix A. Staff interviews: Interview schedule

Stakeholders Interview Outline

Version 2: 31st October 2014

Participants:

Stakeholders within organisations that are involved on a managerial/ governance level for incorporating independent nurse prescribing and patient group directions within sexual health services.

Venue:

If the researcher is able to easily attend the participants' preferred address then they will be given the choice of a face to face or telephone interview. If travelling to the participants' address is difficult then they will be invited to a telephone interviews. Interviews will take place at the most convenient times for the participants.

Agenda:

- Thank participants for their interest in the study and their time.
- Introduce myself and give brief explanation of the research project.
- General housekeeping
    - Ensure the participant has read the information sheet before the interview and has signed the consent form.
    - confirmation that the following section will be audio taped,
    - anonymity of participants within the written section of the study
    - freedom of expressing personal opinions without prejudice.
    - Opportunity to ask any further questions before beginning.

[5 minutes]

Question prompts:

1. Can you discuss your perception of how your service(s) are affected by nurses being able to provide medication by independent nurse prescribing and/ or patient group directions?

   [20 minutes]
2. What are the benefits and concerns of integrating independent nurse prescribing within your organisation(s)?

   [20 minutes]
3. What are the benefits and concerns of integrating and maintaining patient group directions within your organisation(s)?

   [20 minutes]

Maximum total duration: 65 minutes.

Thank participants for their input.

Appendix B. Staff interviews: Participant information sheet

Task 1: Stakeholder Interviews Participant Information Sheet

Version 4.2: 9th July 2015

Study title

A comparison in the clinical application, patient experience and health economics between independent nurse prescribing and patient group directions in sexual health services

Invitation and brief summary
We'd like to invite you to take part in a research study because you are a senior NHS stakeholder involved with integrating nurse prescribing and/ or patient group directions within the sexual health department. Joining the study is entirely up to you, before you decide we would like you to understand why the research is being done and what it would involve for you. The researcher will go through this information sheet with you, to help you decide whether or not you would like to take part and answer any questions you may have. We'd suggest this should take about 10 minutes. Please feel free to talk to others about the study if you wish.

Available evidence on how nurses' ability to independently deliver medicines affects services and patient experience is limited. This study aims to explore these issues in the context of sexual health clinics. The study involves mixture of seven methods to explore this topic from different perspectives. You are being invited to participate in Task 1: NHS Stakeholders' Interview; either face to face or by telephone lasting approximately 1 hour. Your experiences in these areas will be audio taped and used to provide valuable information to form the basis of the study.

What's involved?
You will be asked to participate in a face-to-face or telephone interview at a convenient time for you. There are a total of 5 research sites; a senior NHS stakeholder at each site will be invited to participate. You will be asked to share your experiences relating to the governance related to the integration of nurse prescribing and/ or PGDs into clinical practice, which will be audio taped, transcribed verbatim and compared against the other participants.
You will be requested to sign a consent form prior to participation and after a period of 48 hours has passed following reading this information sheet.

What are the possible benefits of taking part?
There is no direct benefit but your help may allow us to have a deeper understanding of the governance issues relating to the integration of nurses delivering medication independently.

What are the possible disadvantages and risks of taking part?
There is a time commitment issue, however a telephone based meeting aims to reduce the impact on your workload. Should you prefer a face-to-face interview this will be done at a time and venue to cause minimal disruption to your work load. As part of that review unsafe practice may be discovered. Any such occurrences will be discussed with you, and if appropriate a senior manager. Your opinion may not be shared among other participants that are interviewed, however all opinions are valuable, and it is recognised not all users will have the same experience.

What if there is a problem?
If you have a concern about any aspect of this study, you should ask to speak to the researcher who will do their best to answer your questions. In the first instance please contact Adam Black (Researcher) on 07XXXXXXXXX or adam.black@kcl.ac.uk. Should you have any further concerns, please contact: Professor Christine Norton (Principle Investigator) by email: Christine.norton@kcl.ac.uk

If you have a complaint, you should talk to Adam Black who will do his best to answer your questions. If you remain unhappy, you may be able to make a formal complaint through the NHS complaints procedure. Details can be obtained through the Patient Advice & Liaison Service [insert local details]

This study is sponsored by King's College London. The sponsor will at all times maintain adequate insurance in relation to the study independently. Kings College London, through its own professional indemnity (Clinical Trials) and no fault compensation.

What will happen if I don't want to carry on with the study?
Participation is entirely voluntary. Should you decide that you do not wish to participate, or later withdraw, you do not need to provide a rationale and you will not be penalised in any way.

Will my information be kept confidential?
Your participation will be treated confidentially. Your interview will have a study ID allocated to it, traceable only by the researcher. The device used to record the interview will encrypt the data. The audio recording will be transcribed verbatim and undergo thematic analysis. Both the audio file and transcription will be securely stored on a Virtual Private Network at Imperial College Healthcare NHS Trust, which is accessible only by Adam Black and Professor Christine Norton. Responses from all participants will be combined for analysis and you will not be named in any reports or publications. All information which is collected during the course of the research will be kept confidential, in accordance with the Data Protection Act 1998. Should you wish a copy of your transcribed interview please contact Adam Black.

What will happen to the results of this study?
The results of the study will be reviewed against other participants and undergo descriptive analysis, statistical testing and a health economics review. The data will be used to write up a PhD thesis and be disseminated in relevant professional journals and conferences.

Who is organising and funding the research?
The study is organised by Adam Black, a Consultant Nurse in Sexual Heath prior to undertaking a PhD fellowship. This study is funded through a Clinical Doctoral Research Fellowship by the National Institute of Health Research & Health Education England (NIHR/HEE). The study forms part of a PhD programme at the King's College London undertaken by Adam Black.

Who has reviewed this study?
All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by Wales 4 Research Ethics Committee, ref: 15/WA/0120. The study was also reviewed by the department's Research & Development prior to starting.

Further information and contact details
Specific advice about this research study: please contact Adam Black on 07XXXXXXXXX or by email at adam.black@kcl.ac.uk. Should you have any further concerns please contact the Principal Investigator at King's College London, Professor Christine Norton, by email: christine.norton@kcl.ac.uk

Advice as to whether they should participate: Should you require any independent advice on participating in research please speak to your line manager or your organization's Research & Development team.

Please keep for your records

Appendix C. Staff interviews: Consent form

Task 1: NHS Stakeholder Interview Consent Form

(Form to be on headed paper)

Centre Number:

Study Number:

Participant Identification Number for this project:

CONSENT FORM

Title of Project: A comparison in the clinical application, patient experience and health economics between independent nurse prescribing and patient group directions in sexual health services:

Name of Researcher: Adam Black

Please initial box

1. I confirm that I have read the information sheet dated 6th March 2015 (version 4) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected. ☐
3. I understand that my interviews will be audio taped, transcribed and the content used for research purposes, but my details will be anonymised in any reporting of the content. ☐
4. I agree to take part in the above study. ☐

_____	_____	_____
Name of Participant	Date	Signature
_____	_____	_____
Name of Person taking consent	Date	Signature

When completed: 1 for participant; 1 for researcher site file

Version 4: 6th March 2015

Appendix D. Staff questionnaire: Participant information sheet

Task 2 Staff Questionnaire Participant Information Sheet

Version 6.1; 9th July 2015

Study title
A comparison in the clinical application, patient experience and health economics between independent nurse prescribing and patient group directions in sexual health services.

Invitation and brief summary
We'd like to invite you to take part in a research study because you are a nurse using independent nurse prescribing or patient group directions in a sexual health department. Joining the study is entirely up to you, before you decide we would like you to understand why the research is being done and what it would involve for you. The researcher will go through this information sheet with you, to help you decide whether or not you would like to take part and answer any questions you may have. We'd suggest this should take about 10 minutes. Please feel free to talk to others about the study if you wish.
Available evidence on how nurses' ability to independently deliver medicines affects services and patient experience is limited. This study aims to explore these issues in the context of sexual health clinics. You are being invited to participate in a study designed to explore how independent nurse prescribing and patient group directions are used by nurses in sexual health services. The study involves mixture of methods to explore this topic from different perspectives. You are being invited to participate in Task 2: Staff Questionnaire because you have been identified as a nurse working within sexual health who uses independent nurse prescribing or patient group directions. All nurses that are able to independently deliver medication in your department are being invited to participate.

What's involved?
If you agree to take part in this study, you are requested to complete a questionnaire which asks about your skills, experience and opinions of how nurses' independent delivery of medication affects practice. This questionnaire will take approximately 20 minutes to complete.

What are the possible benefits of taking part?
There is no direct benefit but your help may allow us to have a deeper understanding of how nurses in sexual health are able to independently deliver medications.

What are the possible disadvantages and risks of taking part?
It is expected only to take approximately 20 minutes to complete.

What if there is a problem?
If you have a concern about any aspect of this study, you should ask to speak to the researcher who will do their best to answer your questions. In the first instance please contact Adam Black (Researcher) on 07XXXXXXXXX or adam.black@kcl.ac.uk. Should you have any further concerns, please contact: Professor Christine Norton (Principle Investigator) by email: Christine.norton@kcl.ac.uk

If you have a complaint, you should talk to Adam Black who will do his best to answer your questions. If you remain unhappy, you may be able to make a formal complaint through the NHS complaints procedure. Details can be obtained through the Patient Advisory Liaison Service [insert local details].

This study is sponsored by King's College London. The sponsor will at all times maintain adequate insurance in relation to the study independently. Kings College London, through its own professional indemnity (Clinical Trials) and no fault compensation.

What will happen if I don't want to carry on with the study?
Participation is entirely voluntary. Should you decide that you do not wish to participate you do not need to provide a rationale and you will not be penalised in any way.

Will my information be kept confidential?
Your participation will be treated confidentially. Your questionnaire will be analysed with other responses from all participants and combined for analysis. You will not be named in any reports or publications. The back page inviting you to participate in the next stages will be removed before the questionnaire is reviewed. All information which is collected during the course of the research will be kept confidential, in accordance with the Data Protection Act 1998. All electronic data generated will be stored on a secure Virtual Private Network at Imperial College Healthcare NHS Trust, accessible only by Adam Black and Professor Christine Norton. All hardcopies will be destroyed as NHS confidential waste after being scanned and electronically stored.

What will happen to the results of this study?
The results of the study will be reviewed against other participants and undergo descriptive analysis, statistical testing and a health economics review. The data will be used to write up a PhD thesis and be disseminated in relevant professional journals and conferences.

Who is organising and funding the research?
The study is organised by Adam Black, a Consultant Nurse in Sexual Heath prior to undertaking a PhD fellowship. This study is funded through a Clinical Doctoral Research Fellowship by the National Institute of Health Research & Health Education England (NIHR/HEE). The study forms part of a PhD programme at the King's College London undertaken by Adam Black.

Who has reviewed this study?
All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by Wales 4 Research Ethics Committee, ref: 15/WA/0120. The study was also reviewed by the department's Research & Development prior to starting.

Further information and contact details

Specific advice about this research study: please contact Adam Black on 07XXXXXXXXX or by email at adam.black@kcl.ac.uk. Should you have any further concerns please contact the Principal Investigator at King's College London, Professor Christine Norton, by email: christine.norton@kcl.ac.uk

Advice as to whether they should participate: Should you require any independent advice on participating in research please speak to your line manager or your organisation's Research & Development team.

Please keep for your records

Appendix E. Staff questionnaire: Independent nurse prescribers

Questionnaire for Sexual Health Independent Nurses Prescribers
Version 4.3: 6th March 2015

Dear Colleague, Reference:

Thank you for taking the time to complete this survey. Once you have completed it please hand it back to the researcher or post it back in the envelope provided.

This survey is intended only for nurses who are independent prescribers in sexual health. If you do not deliver medications in this way please return the questionnaire to the researcher. If you use Patient Group Directions (without an independent prescribing qualification) please ask the researcher for the questionnaire for nurses using PGDs.

Please tick the relevant answers.

Section 1: Background

1. How do you currently independently deliver medication?

- Independent nurse prescribing ☐
- Patient Group Directions (PGDs) ☐
- Both nurse prescribing & PGDs ☐
- Other (e.g. supplementary prescribing) (Specify): ☐

2. Are you

- Female ☐
- Male ☐
- Rather not say ☐

3. What age range are you in (years)?

- Under 25 ☐
- 25-34 ☐
- 35-44 ☐
- 45-54 ☐
- 55-64 ☐
- 65 and over ☐

4. At what grade are you currently practising?

- Band 5 ☐
- Band 6 ☐
- Band 7 ☐
- Band 8 or 9 ☐

5. What is the highest level at which you have studied?

- Diploma (level 5) ☐
- Degree (level 6) ☐
- Master's (level 7) ☐
- PhD ☐

6. For how many years have you…

Been a qualified nurse	yrs
Worked in clinical practice	yrs
Worked in sexual health	yrs
Been a qualified prescriber	yrs
Previously used PGDs	yrs

7. What clinical competencies do you currently have, in line with your department's training programme (tick all that apply)?

Working towards completing local clinical competencies	☐
Asymptomatic GU screening only	☐
Simple/ intermediate symptomatic GU management	☐
Full symptomatic GU management	☐
Basic contraception (e.g. pills, injections)	☐
Advanced contraception (e.g. implants, coils)	☐

Section 2: Views on independent medication delivery

Please read the following statements and circle the number which most accurately represents your view.

Statement	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
Being able to independently deliver medication makes my clinical role easier	1	2	3	4	5
Being able to independently deliver medication is essential for my current role	1	2	3	4	5
I feel my skills in prescribing are being used effectively	1	2	3	4	5
I believe patients obtain a better experience because I deliver medications independently	1	2	3	4	5
I am confident in my ability to independently deliver medication	1	2	3	4	5
Confidence in my clinical practice has increased since I have been able to deliver medication independently	1	2	3	4	5
Training enabling me to deliver medication independently was adequate	1	2	3	4	5
I am supported in meeting my continuing professional development needs to deliver medicines independently	1	2	3	4	5
Independent medicines delivery has resulted in me feeling more satisfied in my role	1	2	3	4	5
I would recommend nurse prescribing to a department not using it	1	2	3	4	5
Overall I feel the effort required in training to deliver medications independently was worthwhile	1	2	3	4	5

Section 3: About Becoming an Independent Nurse Prescriber

1. What motivated you to undertake the prescribing course? (tick all that apply)

- Enhance clinical skills ☐
- Improve patient experience/ journey ☐
- Obtain academic credits ☐
- Expectation from role/ employer ☐
- Increase my knowledge of medicines/ pharmacology ☐
- Facilitate service development ☐
- Improve satisfaction in your role ☐
- Remove existing restrictions to medication delivery ☐
- Other (specify)

2. Which University and year did you complete your independent nurse prescribing course (and if known how many university level and credits was it)?

University	
Year	
Credits & Level	Credits: 15 / 20 / 30 / 40 / 60 Level: 6 / 7

3. Who paid the university course fees?

Employer paid the entire fees ☐

I personally paid the entire fees ☐

Employer initially paid fees, but I reimbursed them (what percentage/ cost?) ☐

This was split between myself and my employer (what was the percentage split?) ☐

I obtained funding from another source (please specify) ☐

4. Can you provide details on the level and type of professional support provided by your organisation for the clinical component of the prescribing course?

A. What was the role/ grade of your designated medical practitioner (DMP)?

B. About how many of the 12 clinical training days did you spend with your DMP?

10 or more ☐

7 to 9 ☐

3 to 6 ☐

Less than 3 ☐

Don't know? can't remember ☐

C. Did you require formal support from your colleagues other than your DMP?

Yes ☐ No ☐

D. **If Yes,** what were the job titles/ grades of these colleagues	How many hours did they support you?

5. How many study days (if any) did your employer give you in order to complete the prescribing course?

days

6. **Approximately how many days did you spend studying for the INP qualification, or completing assessments / your portfolio, *in addition to* the designated 26 university and e-learning days and the study days provided by your employer?**

days

7. **Can you provide an estimate of how much you spent out-of-pocket completing your prescribing training programme?**

Additional travelling expenses (over normal travel)	
Accommodation	
Books	
Stationery/ materials	
Other (please specify)	

8. **How much of these out-of-pocket expenses were reimbursed by your employer?**

9. **Please add any further comments you feel would benefit the study**

Expression of interest in the next phase of the research

Please note that for confidentiality reasons this page will be removed prior to reviewing responses

I am looking for volunteers to participate in the next phase of the study which will explore how nurse prescribing and PGDs are used by sexual health nurses in clinical practice. Volunteers will be asked to complete a simple 'tick box' diary over a 2 week period and distribute a questionnaire to their patients.

Please indicate if you would be willing to consider participating in this phase of the research. Submitting an expression of interest will not be binding and you will be free to withdraw at any stage.

I am NOT interested in taking part in the next phase of the research (no further details required) ☐

I would be interested in taking part in the next phase of the research (please complete section below) ☐

Your name:

Email address:

Name of the Trust in which you work:

Do you use: **Prescribing** ☐ **PGD** ☐

THANK YOU for your time and co-operation in completing this questionnaire.

Please place your completed questionnaire in the enclosed envelope and return to Adam Black.

If you have any further questions, please do not hesitate to contact Adam Black on:

Telephone: 07979401077

Email: adam.black@kcl.ac.uk

Address: Jefferiss Wing Centre for Sexual Health, St. Mary's Hospital, Praed Street, London, W2 1NY.

Appendix F. Staff questionnaire: Patient group direction users

Questionnaire for Sexual Health Patient Group Direction Users
Version 4.3: 6th March 2015

Dear Colleague, Reference:

Thank you for taking the time to complete this survey. Once you have completed it please hand it back to the researcher or post it back in the envelope provided.

This survey is intended for nurses in sexual health who use Patient Group Directions and who have *NOT* completed an independent nurse prescribing course. If you use independent nurse prescribing please ask the researcher for the prescribers' questionnaire. If you do not use PGDs, please return the questionnaire to the researcher.

Please tick the relevant answers.

Section 1: Background

1. How do you currently independently deliver medication?

- Patient Group Directions (PGDs) ☐
- Patient Specific Directions (PSDs) ☐
- Other (Specify): ☐

2. Are you

- Female ☐
- Male ☐
- Rather not say ☐

3. What age range are you in (years)?

- Under 25 ☐
- 25-34 ☐
- 35-44 ☐
- 45-54 ☐
- 55-64 ☐
- 65 and over ☐

4. At what grade are you currently practising?

- Band 5 ☐
- Band 6 ☐
- Band 7 ☐
- Band 8 or 9 ☐

5. What is the highest level at which you have studied?

- Diploma (level 5) ☐
- Degree (level 6) ☐
- Master's (level 7) ☐
- PhD ☐

6. For how many years have you…

Been a qualified nurse	yrs
Worked in clinical practice	yrs
Worked in sexual health	yrs
Been using PGDs	yrs

7. What clinical competencies do you currently have, in line with <u>your department's</u> training programme (tick all that apply)?

Working towards completing local clinical competencies ☐

Asymptomatic GU screening only ☐

Simple/ intermediate symptomatic GU management ☐

Full symptomatic GU management ☐

Basic contraception (e.g. pills, injections) ☐

Advanced contraception (e.g. implants, coils) ☐

Section 2: Views on independent medication delivery

Please read the following statements and circle the number which most accurately represents your view. As providing medication with PGDs is not prescribing, the term 'independently deliver medication' is used to describe the supply/ administration of medicines using PGDs.

Statement	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
Being able to independently deliver medication makes my clinical role easier	1	2	3	4	5
Being able to independently deliver medication is essential for my current role	1	2	3	4	5
I feel my skills in prescribing are being used effectively	1	2	3	4	5
I believe patients obtain a better experience because I deliver medications independently	1	2	3	4	5
I am confident in my ability to independently deliver medication	1	2	3	4	5
Confidence in my clinical practice has increased since I have been able to deliver medication independently	1	2	3	4	5
PGD training was adequate to prepare me to deliver medication independently	1	2	3	4	5
I am supported in meeting my continuing professional development needs to deliver medicines independently	1	2	3	4	5
Independent medication delivery has resulted in me feeling more satisfied in my role	1	2	3	4	5
I would recommend PGDs prescribing to a department not using them	1	2	3	4	5
Overall I feel the effort required in training to deliver medications independently was worthwhile	1	2	3	4	5

Section 3: About learning to use Patient Group Directions

1. **What motivated you to start using PGDs? (tick all that apply)**

Enhance clinical skills ☐

Improve patient experience/ journey ☐

Expectation from role/ employer ☐

Increase my knowledge of medicines/ pharmacology ☐

Facilitate service development ☐

Improve satisfaction in your role ☐

Remove existing restrictions to medication delivery ☐

Other (specify)

2. **Did you receive formal training to use PGDs?**

No ☐

Can you detail how you learned to use PGD:

(Please skip question 3)

Yes ☐ **Continue to question 3–**

3. **Can you provide information about your PGD training? (please complete relevant sections)**

Type of training	Yes/No (tick)	Number of colleagues training with you	Number of hours
Class teaching/ presentation			
Question & Answer			
Workshops			
Self-directed reading			
E-learning			
One-to-one teaching/ discussions			
Other (specify)			

4. **How many study days (if any) did your employer give you in order to complete the PGD training?**

days

5. **What was the role/ grade of the PGD trainer (if you had one)?**

6. **Can you provide information about your PGD assessment? (please complete relevant sections)**

Type of training	Yes/No (tick)	Role/grade of the assessor
Case study		
Objective Structured Clinical Examination (OSCE)		
Retrospective notes audit		
Exam/ assessment paper		
Reflection paper		
No formal assessment		
Other (specify)		

7. **Approximately how many days did you spend studying for the PGDs, or completing assessments, *in addition to* the training time and study days that you have reported in questions 3 and 4?**

days

8. **Can you provide an estimate of how much you spent out-of-pocket completing your PGD training?**

Additional travelling expenses (over normal travel)	
Accommodation	
Books	
Stationery/ materials	
Other (please specify)	

9. **How much of these out-of-pocket expenses were reimbursed by your employer?**

10. **How likely are you to complete the independent nurse prescribing course in the future?**

Very unlikely	Unlikely	Neutral	Likely	Very likely
1	2	3	4	5

11. **Please add any further comments you feel would benefit the study**

Expression of interest in the next phase of the research

Please note that for confidentiality reasons this page will be removed prior to reviewing responses

I am looking for volunteers to participate in the next phase of the study which will explore how nurse prescribing and PGDs are used by sexual health nurses in clinical practice. Volunteers will be asked to complete a simple 'tick box' diary over a 2 week period and distribute a questionnaire to their patients.

Please indicate if you would be willing to consider participating in this phase of the research. Submitting an expression of interest will not be binding and you will be free to withdraw at any stage.

I am NOT interested in taking part in the next phase of the research (no further details required) ☐

I would be interested in taking part in the next phase of the research (please complete section below) ☐

Your name:

Email address:

Name of the Trust in which you work:

Do you use: **Prescribing** ☐ **PGD** ☐

THANK YOU for your time and co-operation in completing this questionnaire.

Please place your completed questionnaire in the enclosed envelope and return to Adam Black.

If you have any further questions, please do not hesitate to contact Adam Black on:

Telephone: 07979401077

Email: adam.black@kcl.ac.uk

Address: Jefferiss Wing Centre for Sexual Health, St. Mary's Hospital, Praed Street, London, W2 1NY.

Appendix G. Clinical diary: Data collection tool

Medication Delivery in Sexual Health: Clinical Activity Diary

Sexual Health Clinic Site: Nurse code:

Session date/ start time: Clinic: Study number: INP / PGD

Patient Clinic ID	New / FU	Medication provided	Advice from other	Medication delivery	Time (minutes) patient related			Patient Survey
					Face-to-face	Non Pt facing	With other profession	
	New FU	Yes No	No CM Med D N P HA	Independent Rx from: D N P HA No PGD				Yes, ref Not given
	New FU	Yes No	No CM Med D N P HA	Independent Rx from: D N P HA No PGD				Yes, ref Not given
	New FU	Yes No	No CM Med D N P HA	Independent Rx from: D N P HA No PGD				Yes, ref Not given
	New FU	Yes No	No CM Med D N P HA	Independent Rx from: D N P HA No PGD				Yes, ref Not given
	New FU	Yes No	No CM Med D N P HA	Independent Rx from: D N P HA No PGD				Yes, ref Not given
	New FU	Yes No	No CM Med D N P HA	Independent Rx from: D N P HA No PGD				Yes, ref Not given

Identify the type of advice obtained: CM: Clinical Management; Med: Medication
D: Doctor; N: Nurse; P: Pharmacist; HA: Health Advisor Time = estimated minutes

Version 6.1: October 2014

Appendix H. Clinical diary: Explanatory notes

Sexual Health Nurse Activity Diary: Explanatory Notes V6.1: October 2014

Dear Colleague,

Thank you for agreeing to complete a brief clinical diary for the above study. The diary has been designed to gather data on your clinical activity, frequency and independence of medication provision, and to record the distribution of patient questionnaires. I would be grateful if you would complete the diary every time you conduct **a patient-facing clinical session**, over a period of 2 weeks.

This sheet provides explanatory notes to assist you in completing the diary. Should you have any further questions please contact Adam Black on 07XXXXXXXX or adam.black@kcl.ac.uk

Subject heading	Pre-set data	Explanation
Sexual Health Clinic Site		Name of the department / clinic where your patient facing session is occurring
Nurse code		Check that a code has been added to identify you
INP/PGD		Circle as appropriate to indicate if you are an independent nurse prescriber or PDG user
Session date/ start time		State the date of the clinic session and its start time
Clinic		State the name of the specific clinic you are undertaking
Patient ID	Clinic number & DOB	For each new patient please provide '**Clinic ID Number**' & **date of birth** or an ID sticker
New / FU	New	Circle if a new episode of care
	FU	Circle if it's a follow-up episode of care
Medication provided	Yes	CIRCLE IF MEDICATION WAS DELIVERED
	No	CIRCLE IF MEDICATION WAS NOT DELIVERED
Advice	No	Circle if you did not require any advice from a colleague
	CM	Circle if you needed advice on the clinical management of the patient
	Med	Circle if you needed advice on any form of medication delivery
	D N P HA	Circle the appropriate abbreviation relating to what colleague you obtained advice from: D: Doctor N: Nurse P: Pharmacist HA: Health Advisor
Medication delivery	Independent	Circle if you independently delivered the medication
	Rx from: D N P HA	Circle the appropriate abbreviation relating to what colleague you obtained a prescription from: D: Doctor N: Nurse P: Pharmacist HA: Health Advisor
	No PGD	**Circle only if you use PGDs** where medication was indicated but **NOT** covered by the PGD.
Time (minutes) patient related		Please provide an estimate of how many minutes spent on the patient in relation to 'Face-to-face'; 'Non pt facing' & time with other professional
Face-to-face		How long (minutes) you spent in consultation with the patient (inc. history, examination and results)
Non Pt facing		How long (minutes) you spent on this patient, but NOT face –to –face (e.g. writing notes, referral letters, etc.)
With other profession		How long (minutes) you spent with the other professional indicated in the 'Advice' column. Record 0 (zero) minutes if you sought no advice for this patient.
Please hand a questionnaire to patients you deliver medication to at the end of the consultation		
Patient questionnaire	Yes, ref:	Detail if you gave the patient a questionnaire when delivering medication; record the questionnaire number
	Not given	Circle if you did not give a questionnaire. If possible please detail reason for not giving them one.

Appendix I. Clinical diary: Participant information sheet

Task 3A Clinical Diary: Participant Information Sheet

Version 8.2: 1st February 2016

Study title
A comparison in the clinical application, patient experience and health economics between independent nurse prescribing and patient group directions in sexual health services

Invitation and brief summary
We'd like to invite you to take part in a research study because you are a nurse who is using independent nurse prescribing or patient group directions in the sexual health department. Following completion of the questionnaire you expressed an interest in taking part in this next phase of the research. Joining the study is entirely up to you, before you decide we would like you to understand why the research is being done and what it would involve for you. The researcher will go through this information sheet with you, to help you decide whether or not you would like to take part and answer any questions you may have. We'd suggest this should take about 10 minutes. Please feel free to talk to others about the study if you wish.
Available evidence on how nurses' ability to independently deliver medicines affects services and patient experience is limited. This study aims to explore these issues in the context of sexual health clinics. The study involves a mixture of methods to explore this topic from different perspectives. You are being invited to participate in Task 3A: Clinical Diary. This involves recording simple information during your normal clinical duties for a period of 2 weeks. You will also be requested to hand out patient experience questionnaires if you deliver medication

What's involved?
If you agree to take part in this study, you are requested to complete a simple diary for a period of two weeks to record your normal clinical duties. Completion of the diary requires the patient's clinic number, approximate consultation times and 'circling' responses to questions relating to how medication was given and if you received any support from any of your colleagues. Diary booklets can be handed to the researcher at the end of the two week data collection period, or posted in the freepost envelope provided. You will also be requested to distribute a patient experience questionnaire. The researcher will then use the diaries to explore how nurses deliver medication in terms of frequency and independence, and **may be used** to identify a sample of patient records.

What are the possible benefits of taking part?
There is no direct benefit but your help may allow us to have a deeper understanding of how independent nurse prescribing and patient group directions are used in clinical practice by sexual health nurses.

What are the possible disadvantages and risks of taking part?
It is expected to take less than 1 minute to complete the diary at the end of every patient facing consultation.

What if there is a problem?
If you have a concern about any aspect of this study, you should ask to speak to the researcher who will do their best to answer your questions. In the first instance please contact Adam Black (Researcher) on 07XXXXXXXXX or adam.black@kcl.ac.uk. Should you have any further concerns, please contact: Professor Christine Norton (Principle Investigator) by email: Christine.norton@kcl.ac.uk
If you have a complaint, you should talk to Adam Black who will do his best to answer your questions. If you remain unhappy, you may be able to make a formal complaint through the NHS complaints procedure. Details can be obtained through the Guy's and St Thomas' Patient Advisory Liaison Service (PALS) on 0207 1887188, address: PALS, KIC, Ground floor, north wing, St Thomas' Hospital, Westminster Bridge Road, London, SE1 7EH.

This study is sponsored by King's College London. The sponsor will at all times maintain adequate insurance in relation to the study independently. Kings College London, through its own professional indemnity (Clinical Trials) and no fault compensation.

What will happen if I don't want to carry on with the study?
Participation is entirely voluntary. Should you decide that you do not wish to participate, or later withdraw, you do not need to provide a rationale and you will not be penalised in any way.

Will my information be kept confidential?
Your participation will be treated confidentially. Your participation in the clinical diary will be coded using a study ID, traceable only by the researcher. Responses from all participants will be combined for analysis and you will not be named in any reports or publications. All information which is collected during the course of the research will be kept confidential, in accordance with the Data Protection Act 1998. In cases where queries about your practice exists may result in the researcher discussing this with you or your manager for further clarification, however you will not be named in the research reports. All electronic data generated from the study will only be stored on a secure Virtual Private Network at Imperial College Healthcare NHS Trust, accessible only by Adam Black and Professor Christine Norton. Hardcopies will be destroyed as confidential NHS waste after they have been scanned and electronically stored.

What will happen to the results of this study?
Data from the clinical diary will be collected on a specifically designed database. The results will be reviewed against other participants and undergo descriptive analysis, statistical testing and a health economics review. The data will be used to write up a PhD thesis and be disseminated in relevant professional journals and conferences.

Who is organising and funding the research?
The study is organised by Adam Black, a Consultant Nurse in Sexual Heath prior to undertaking a PhD fellowship. This study is funded through a Clinical Doctoral Research Fellowship by the National Institute of Health Research & Health Education England (NIHR/HEE). The study forms part of a PhD programme at the King's College London undertaken by Adam Black.

Who has reviewed this study?
All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by Wales 4 Research Ethics Committee, ref: 15/WA/0120. The study was also reviewed by the department's Research & Development prior to starting.

Further information and contact details

Specific advice about this research study: please contact Adam Black on 07XXXXXXXXX or by email at adam.black@kcl.ac.uk. Should you have any further concerns please contact the Principal Investigator at King's College London, Professor Christine Norton, by email: christine.norton@kcl.ac.uk

Advice as to whether they should participate: should you require any independent advice on participating in research please speak to your line manager or your organisation's Research & Development team.

Please keep for your records

Appendix J. Clinical diary: Consent form

Trust Logo

Task 3A Clinical Diary: Consent Form
Version 8.2: 1st February 2016

Centre Number:

Study Number:

Participant Identification Number for this project:

CONSENT FORM

Title of Project: A comparison in the clinical application, patient experience and health economics between independent nurse prescribing and patient group directions in sexual health services: **Task 3A Clinical Diary**

Name of Researcher: Adam Black

Please initial box

1. I confirm that I have read the information sheet dated **1st February 2016 (version 8.2)** for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my legal rights being affected. ☐
3. I understand that relevant sections of medical notes created by me and data collected during the study may be looked at by the researcher or from the NHS Trust where it is relevant to the research. I give permission for these individuals to have access records completed by me. ☐
4. I agree to take part in the above study. ☐

_____	_____	_____
Name of Participant	Date	Signature
_____	_____	_____
Name of Person taking consent	Date	Signature

When completed: 1 for participant; 1 for researcher site file

Appendix K. Clinical notes review: Data collection field list

Field name	Description/ rationale for data collection
ID	Unique entry number
Entry date	Automated date of entry's creation
Site	Details of entry's research site
Entry purpose	Differentiation of data collected for clinical notes, observations or local random review
Delivery method	Was care delivered by INP or PGD user, and was medication given?
Participant ID	Coded nurse identifier
Gender	What is the patients' gender?
Age	How old was the patient on date of attendance?
Ethnic origin	What was the patient's registered ethnic origin?
Sexual orientation	What was the patient's registered sexual orientation?
Attendance date	What date did the patient attend?
Episode type	Was the patient attending for new or follow-up care episode?
Symptoms	Was the patient attending with symptoms?
PMH	Was the patient's past medical history documented?
Meds	Was the patient's concurrent medication documented?
Allergy	Was the patient's allergies (or lack of) documented?
PT risk	Where applicable, was pregnancy/ breast feeding risk documented
PMH comments	Detail any PMH, meds, allergies, pregnancy issues
Diagnosis (1-5)	Details of diagnose(s); five entry fields given
Diagnosis comments	Further details/ comments related to diagnosis
Drug name (1-4)	Name of the drug delivered; four entry fields given
Dose (1-4)	Dose of the drug delivered; four entry fields given
Frequency (1-4)	Frequency of the drug delivered; four entry fields given
Length (1-4)	Duration of the drug's regimen; four entry fields given
Signature	Signature on the page where documentation of the drug delivered; four entry fields given
INP/ PGD	Was the drug delivered through INP or PGD
Drug comments	Further details/ comments related to medication
Advice	Was there any documentation that the nurse sought advice
Independent completion	Was the episode of care completed autonomously?
Clinical advice obtained	Did the nurse seek clinical advice?
Medication advice	Did the nurse seek medication advice?
Specialist referral	Did the nurse make a specialist referral for the patient?
Non-provision	Was medication indicated but not given?
Non-provision comments	Further details/ comments related to non-provision of medication when it was indicated
Indication	MAI: Is there an indication for the drug?
Effective	MAI: Is the medication effective for the condition?
Dosage	MAI: Is the dosage correct?
Directions correct	MAI: Are the directions correct?
Directions practical	MAI: Are the directions practical?

Field name	Description/ rationale for data collection
Drug-drug interaction	MAI: Are there clinically significant drug-drug interactions?
Drug-disease interaction	MAI: Are there clinically significant drug-disease interactions?
Duplication	MAI: Is there unnecessary duplication with other drugs?
Duration	MAI: Is the duration of therapy acceptable
Cost	MAI: Is this drug the least expensive alternative compared to others of equal utility?
MAI comments	Each MAI question had a separate section to add further details/ comments
PGD limits	Was the medication delivered within the PGD's restrictions (PGD users only)
PGD limits comments	Further details/ comments related to PGD use
INP vs PGD	Was the PGD suitable for PGD users / if an INP used a PGD could they have managed the patient?
Appropriate	Overall, was the episode of care and medication delivery appropriate?
Safe	Overall, was the episode of care and medication delivery safe?
Overall	Overall, was the episode of care and medication delivery safe & appropriate?
Overall comments	Further details/ comments related to overall safety and appropriateness
Clarification	Was further clarification/ discussion needed/ sought?
Unplanned re-attendance	Did the patient return for an unplanned visit relating to the episode of care?
Unplanned comment	Further details/ comments related to unplanned visit

ID= identifier, INP= independent nurse prescriber, MAI= Medication Appropriateness Index, meds= concurrent medications, PGD= patient group direction, PMH= past medical history, PT= pregnancy risk.

Appendix L. Patient experience questionnaire

Patient Experience Questionnaire

INP / PGD Reference: 1317

Thank you for taking the time to complete this survey.

This survey is intended only for patients who have received medication from a nurse. If you **have not** received any medication please tick the box without completing the questionnaire and post it in the box in reception.

I have **NOT** received any medication (return questionnaire without completing it) ☐

I have received medication today ☐

Thinking about your consultation today, please tick the response to each question which best describes your views.

The consultation with the nurse

1. Was the nurse you saw friendly and approachable?

Yes, definitely ☐

Yes, to some extent ☐

No ☐

2. Did you have confidence and trust in the nurse you saw today?

Yes, definitely ☐

Yes, to some extent ☐

No ☐

3. Did the nurse explain the reasons for the medicine you received in a way you could understand?

Yes, completely ☐

Yes, to some extent ☐

No ☐

Did not need an explanation ☐

4. If you had any questions to ask, were you satisfied with the answers?

Yes, definitely ☐

Yes, to some extent ☐

No ☐

Did not have any questions ☐

Did not have an opportunity to ask ☐

5. Did the nurse give you medications WITHOUT speaking to a doctor?

Yes / No / Don't know

If YES, did you feel the nurse had the necessary skills to give you medication without speaking to a doctor?

Yes, definitely ☐

Yes, to some extent ☐

No ☐

Version 4: 6th March 2015

Information about medicines

This section asks for your views on the amount of information you were given about the medicines you received today. Please circle the response to each question which best describes your views.

Information provided

	Too much	About right	Too little	None received	Not applicable
The name of the medicine	1	2	3	4	5
What your medicine is for	1	2	3	4	5
What it does	1	2	3	4	5
How it works	1	2	3	4	5
How long it will take to act	1	2	3	4	5
How can you tell if it is working	1	2	3	4	5
How long you will need to be on your medicine	1	2	3	4	5
How to get a further supply	1	2	3	4	5
Whether the medicine has any unwanted effects (side effects)	1	2	3	4	5
What are the risks of you getting side effects	1	2	3	4	5
What you should do if you experience unwanted side effects	1	2	3	4	5
Whether you can drink alcohol whilst taking this medicine	1	2	3	4	5
Whether the medicine interferes with other medicines you are currently taking	1	2	3	4	5
Whether the medication will make you feel drowsy	1	2	3	4	5
Whether you were able to have sex while taking the medicine	1	2	3	4	5
What you should do if you forget to take a dose	1	2	3	4	5

Please provide any other comments in relation to your consultation today

If you have any specific concerns over the care you received today please ask to speak to the nurse-in-charge or contact the patient advisory team detailed on the front sheet.

Version 4: 6th March 2015

Appendix M. Patient experience questionnaire: Participant information sheet (English version)

Task 5 Patient Experience Questionnaire Participant Information Sheet

Version 4.1: 9th July 2015

Study title
A comparison in the clinical application, patient experience and health economics between independent nurse prescribing and patient group directions in sexual health services

Invitation and brief summary
We'd like to invite you to take part in a research study because you received medication from a nurse who was able to provide medication without speaking to a doctor. Available evidence on how nurses independently deliver medicines affects services and patient experience is limited. This study aims to explore these issues in the context of sexual health clinics. You are being invited to participate in Task 5: Patient Experience Questionnaire as you received medication from a nurse today and we would like feedback on your experience.

What's involved?
If you agree to take part in this study, you are requested to complete a questionnaire about your experience and confidence in receiving your medication. This questionnaire will take approximately 10 minutes to complete.

What are the possible benefits of taking part?
You have the option to enter into a prize draw to potentially win one of ten £20 'High Street Vouchers'. There may be no benefit to you; however we aim to get a better understanding of patients' experience in using the sexual health service.

What are the possible disadvantages and risks of taking part?
It is expected only to take approximately 10 minutes to complete.

What if there is a problem?
If you have a concern about any aspect of this study, you should ask to in the first instance please contact Adam Black (Researcher) on 07XXXXXXXXX or adam.black@kcl.ac.uk. Should you have any further concerns, please contact: Professor Christine Norton (Principle Investigator) by email: Christine.norton@kcl.ac.uk .If you have a complaint about your care you should ask to speak to the nurse in charge who will do their best to answer your questions. If you remain unhappy, you may be able to make a formal complaint through the NHS complaints procedure. Details can be obtained through Patient Advisory Liaison Service [insert local details].
This study is sponsored by King's College London. The sponsor will at all times maintain adequate insurance in relation to the study independently. Kings College London, through its own professional indemnity (Clinical Trials) and no fault compensation.

What will happen if I don't want to carry on with the study?
Participation is entirely voluntary. Your medical care will not be affected should you decide that you do not wish to participate.

Will my information be kept confidential?
Your participation will be treated confidentially. All information which is collected during the course of the research will be kept confidential, in accordance with the Data Protection Act 1998. If you complete the back page inviting you to participate in the optional prize draw please remove this from the questionnaire and post both items in the box in reception. Data from this questionnaire

will be transferred onto an electronic database. All electronic data will be stored on a secure Virtual Private Network at Imperial College Healthcare NHS Trust, accessible only by Adam Black and Professor Christine Norton. Your questionnaire will be scanned and stored electronically. Hardcopies of the questionnaire and prize draw sheets will be destroyed as confidential NHS waste.

What will happen to the results of the study?
The results of the study will be reviewed against other participants and undergo descriptive analysis, statistical testing and a health economics review. The data will be used to write up a PhD thesis and be disseminated in relevant professional journals and conferences.

Who has reviewed this study?
All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by Wales 4 Research Ethics Committee, ref: 15/WA/0120. The study was also reviewed by the department's Research & Development prior to starting.

Further information and contact details

Specific advice about this research study: please contact Adam Black on 07XXXXXXXXX or by email at adam.black@kcl.ac.uk. Should you have any further concerns please contact the Principal Investigator at King's College London, Professor Christine Norton, by email: christine.norton@kcl.ac.uk

Further advice relating to participating in research or about your clinical care: Should you require any independent advice on participating in research please speak to the nurse you were managed by, the nurse in charge or the Patient Advisory Liaison Service.

Please keep for your records

Appendix N. Patient experience questionnaire: Participant information sheet (Welsh version)

Taflen Wybodaeth i Gyfranogwyr am Dasg 5, Holiadur Profiad Cleifion

Fersiwn 4.1: 9fed Gorffennaf 2015

Teitl yr astudiaeth
Cymhariaeth rhwng nyrs yn rhagnodi presgripsiwn yn annibynnol a chyfarwyddiadau grŵp cleifion mewn gwasanaethau iechyd rhywiol o ran cymhwyso clinigol, profiad y claf ac economeg iechyd.

Gwahoddiad a chrynodeb byr
Hoffem eich gwahodd i gymryd rhan mewn astudiaeth ymchwil oherwydd ichi dderbyn meddyginiaeth oddi wrth nyrs a oedd yn gallu darparu meddyginiaeth heb siarad â meddyg. Mae'r dystiolaeth sydd ar gael yn brin ynglŷn ag effaith nyrsys yn darparu meddyginiaethau'n annibynnol ar wasanaethau a phrofiad y claf. Nod yr astudiaeth hon yw edrych ar y materion hyn yng nghyd-destun clinigau iechyd rhywiol. Rydym yn eich gwahodd i gymryd rhan yn Nhasg 5: Holiadur Profiad Cleifion gan ichi dderbyn meddyginiaeth oddi wrth nyrs heddiw ac fe hoffem ni gael eich adborth ar eich profiad.

Beth y mae hyn yn galw amdano?
Os byddwch chi'n cytuno i gymryd rhan yn yr astudiaeth hon, mae gofyn ichi gwblhau holiadur ynglŷn â'ch profiad a'ch hyder wrth dderbyn eich meddyginiaeth. Fe fydd hi'n cymryd rhyw 10 munud i gwblhau'r holiadur hwn.

Beth yw manteision posibl cymryd rhan?
Mae gennych chi'r opsiwn i roi cynnig ar raffl lle gallech chi ennill un o ddeg 'Taleb Stryd Fawr' gwerth £20. Efallai na fydd yr astudiaeth o unrhyw fudd i chi; fodd bynnag, ein nod yw dod i ddeall yn well profiad cleifion o ddefnyddio'r gwasanaethau iechyd rhywiol.

Beth yw anfanteision a risgiau posibl cymryd rhan?
Y disgwyl yw y bydd hi'n cymryd rhyw 10 munud yn unig i'w gwblhau.

Beth os oes yna broblem?
Os oes gennych chi bryder ynglŷn ag unrhyw agwedd ar yr astudiaeth hon, fe ddylech chi yn y lle cyntaf gysylltu ag Adam Black (Ymchwilydd) ar 07XXXXXXXXX neu adam.black@kcl.ac.uk. Os oes gennych chi unrhyw bryderon pellach, yna cysylltwch â'r Athro Christine Norton (Pen Ymchwilydd) trwy e-bost: Christine.norton@kcl.ac.uk

Os oes gennych chi gŵyn ynglŷn â'ch gofal, fe ddylech chi siarad â'r nyrs sydd wrth y llyw a fydd yn gwneud ei (g)orau i ateb eich cwestiynau. Os byddwch chi'n dal i fod yn anhapus, mae'n bosibl y gallwch chi ddefnyddio gweithdrefn y GIG i wneud cwyn ffurfiol. Mae manylion i'w cael trwy'r Adran Gwynion ym Mwrdd Iechyd Prifysgol Caerdydd a'r Fro ffôn: 02920744095, e-bost: concerns@wales.nhs.uk, cyfeiriad: Adran Gwynion, Bwrdd Iechyd Prifysgol Caerdydd a'r Fro, Ysbyty Athrofaol Cymru, Parc y Mynydd Bychan, Caerdydd, CF14 4XW.

Noddir yr astudiaeth hon gan King's College London. Bydd y noddwr, sef King's College London, bob amser yn cynnal yswiriant digonol yn annibynnol o ran yr astudiaeth, trwy ei yswiriant indemniad proffesiynol (Treialon Clinigol) a'i iawndal 'dim bai' ei hun.

Beth fydd yn digwydd os na fydda' i eisiau bwrw ymlaen â'r astudiaeth?
Byddwch chi'n cymryd rhan yn yr astudiaeth hon yn llwyr o'ch gwirfodd. Ni fydd unrhyw effaith ar eich gofal meddygol os byddwch chi'n penderfynu nad ydych chi eisiau cymryd rhan.

A fydd fy ngwybodaeth yn cael ei chadw'n gyfrinachol?
Caiff y rhan y byddwch chi'n ei chwarae yn yr astudiaeth ei thrin yn gyfrinachol. Caiff yr holl wybodaeth a gesglir yn ystod yr ymchwil ei chadw'n gyfrinachol, yn unol â Deddf Diogelu Data 1998. Os byddwch chi'n llenwi'r dudalen gefn sy'n eich gwahodd i gymryd rhan yn y raffl ddewisol, yna datgysylltwch hi o'r holiadur a phostio'r ddwy eitem yn y blwch yn y dderbynfa. Caiff data o'r holiadur hwn eu trosglwyddo i gronfa ddata electronig. Caiff yr holl ddata electronig eu storio ar Rith-rwydwaith Preifat yn Imperial College Healthcare NHS Trust, a dim ond Adam Black a'r Athro Christine Norton a fydd yn gallu eu cyrchu. Caiff eich holiadur ei sganio a'i storio'n electronig. Caiff copïau caled o'r holiadur a dalenni'r raffl eu dinistrio fel gwastraff cyfrinachol y GIG.

Beth fydd yn digwydd i ganlyniadau'r astudiaeth?
Caiff canlyniadau'r astudiaeth eu hadolygu yn erbyn cyfranogwyr eraill a byddan nhw'n destun dadansoddiad disgrifiadol, profion ystadegol ac adolygiad economeg iechyd. Caiff y data eu defnyddio i ysgrifennu thesis PhD a'u rhannu mewn cynadleddau a chyfnodolion proffesiynol.

Pwy sydd wedi adolygu'r astudiaeth hon?
Mae grŵp o bobl annibynnol, o'r enw Pwyllgor Moeseg Ymchwil, yn edrych ar yr holl ymchwil yn y GIG i warchod eich buddion. Mae Pwyllgor Moeseg Ymchwil Cymru 4 wedi adolygu'r astudiaeth hon ac mae'n ffafriol ei farn arni, cyf: 15/WA/0120. Adolygwyd yr astudiaeth hefyd gan dîm Ymchwil a Datblygu'r adran cyn ei chychwyn.

Gwybodaeth bellach a manylion cyswllt

Cyngor penodol ynglŷn â'r astudiaeth ymchwil hon: cysylltwch ag Adam Black ar 07XXXXXXXXX neu drwy e-bost yn adam.black@kcl.ac.uk. Os oes gennych chi unrhyw bryderon pellach, cysylltwch â'r Pen Ymchwilydd yn King's College London, yr Athro Christine Norton, drwy e-bost: christine.norton@kcl.ac.uk

Cyngor pellach ynglŷn â chymryd rhan mewn ymchwil neu ynglŷn â'ch gofal clinigol: Os oes angen unrhyw gyngor annibynnol arnoch chi ynglŷn â chymryd rhan mewn ymchwil, yna siaradwch â'r nyrs fu'n eich rheoli, y nyrs wrth y llyw neu'r Adran Gwynion.

A fyddech cystal â chadw hwn i gyfeirio ato

Appendix O. Observational study: Observational schedule

Data Collection and Analysis for Observational Study

Version 2.1: October 2014

The observational study will include 5 medication delivery consultations from 3 nurse prescribers and 3 PGD users, totally 30 observations for analysis. Each nurse should have more than 1 year experience of independently delivering medications and should be able to manage patients presenting to sexual health services with symptoms. The first 3 nurses in each group who meet these criteria, and who agree to participate, will be selected to undertake the observational phase of the study. The first 5 consultations where medication is delivered will be included and recruitment will stop for that individual nurse. Patients' consultations will be excluded if they:

- Are attending solely as a follow-up attendance (nurse to undertake full consultation) or there is a handover involved (e.g. out of scope or end of shift). If clinical advice is sought this will not be excluded
- Have poor English
- Are aged under 16 years
- Present with safeguarding issues
- Are deemed vulnerable during the consultation (e.g. child abuse, FGM, sexual assault).

Posters will be placed in the waiting rooms advising patients that the study is underway. Patients will be given information leaflets on arrival at the clinic, prior to seeing the nurse, thus allowing them time to consider participating in the study whilst awaiting their consultation. The nurse will ask the patient if they are in agreement that the consultation will be audio-taped before the researcher is invited into the room. Formal written consent from the patient will be obtained, including for the consultation to be audio recorded.

Audio tapes will be transcribed verbatim by the researcher and/ or NHS approved transcribing services that are bound to confidentiality protocols. They will undergo analysis in relation to the following documents:

- A field assessment schedule
- Local policies and documents for the management of sexual health conditions, contraception and patient group directions
- Comparison between consultation transcripts and the clinical records
- Transcripts will be analysed using the Medicines Appropriateness Index
- The SIMS tool used in the patient experience questionnaire will be applied to determine if these items were addressed in observed consultations.

It is expected the Hawthorne Effect will be an issue in this section of the study, however as there is mixed methods adopted each phase is expected to compensate for the weakness in others.

Assessment Schedule for Sexual Health Nurse Consultations

Study Site: **Nurse Study ID:** **Patient ID:** **Date:**

Rating Scale:

1	Accurate, confident, safe practice/ knowledgeable carrying out techniques	**0**	Not done/omitted/not seen/ unsafe practice	**N/A**	Not applicable to this patient/condition

Assessment Schedule:

Assessment & Diagnosis: *Takes a comprehensive history of the patients presenting problem including:*					
	Behavioural indicator competence	**1**	**0**	**N/A**	**Comments**
1	Identifies a chief complaint				
2	Explores presenting symptoms				
3	Explores management of presenting problem to date				
4	Determine previous episodes of presenting problem				
5	Explores past medical history				
6	Explores family/social history				
7	Determines any known allergies & nature of allergic response				
8	Explores current prescribed medication				
9	Explore OTC /herbal products not prescribed				
10	Makes a working or final diagnosis/ decision by considering and systematically deciding between the various possibilities				
11	Identifies a relevant physical examination				
12	Considers psychological, social and environmental factors when establishing treatment options				
13	Considers non-pharmacological treatment options				
14	Requests relevant diagnostic tests				
15	Selects the most appropriate treatment option and/or drug, dose and formulation for the individual patient, assessing the risks and benefits to the patient				
16	Established a plan for reviewing the therapeutic objective/end point of treatment				
TOTAL SCORE					

Communication with the patient					
	Behavioural indicator competence	**1**	**0**	**N/A**	**Comment**
1	Listens to and understands patients beliefs and expectations				
2	Deals sensitively with patients emotions or concerns				
3	Helps patient to make informed choice about their treatment				
4	Explains the nature of the patients' condition and the potential risks and benefits of treatment options				
5	Gives clear instructions to the patient about their medication and how to apply if required (dose, use and duration)				
6	Gives clear instructions to the patient about possible side-effects, and action to take in event of side effects				
7	Shows evidence of understanding the cultural, language and religious implications of prescribing				
8	Shows evidence of using health education initiatives (e.g. avoiding sex and partner notification)				
9	Identifies the present and future needs of the patient/client and shows evidence of planning a strategy with them to meet these needs				
TOTAL SCORE					

Medication issued			**Advice sought**		**Direct dispensing**		**Medication Delivery**			**Duration**
INP	PGD	Other	Clinical	Medication	Yes	No	TTO	Prescription	Administration	

Comments:

Component	Yes	No	N/A	Comment
Field assessment schedule completed; based on NPC				
Episode of care complies with local guidance (inc. PGD)				
Appropriateness of medication; based on MAI				
Is there an indication for the drug				
Is the medication effective for the condition				
Is the dosage correct				
Are the directions correct				
Are the directions practical				
Are there clinically significant drug-drug interactions				
Are there clinically significant drug-disease/ condition interactions				
Is there any unnecessary duplication with other drugs?				
Is the duration of therapy acceptable				
Is the drug the least expensive alternative compared with others of equal utility				
Has the medication been delivered within the limits of the PGD				
Medicines information; based on SIMS				
Name of the medication				
What the medicine is for				
What it does				
How it works				
How long it will take to act				
How can you tell if it is working				
How long you will need to be on your medicine				
How to get a further supply				
Whether the medicine has any unwanted effects (side effects)				
What are the risks of you getting side effects				
What you should do if you experience unwanted side effects				
Whether you can drink alcohol whilst taking this medicine				
Whether the medicine interferes with other medicines you are currently taking				
Whether the medication will make you feel drowsy				
Whether you were able to have sex while taking the medicine				
What you should do if you forget to take a dose				

Appendix P. Observational study: Staff participant information sheet

Task 4 Staff Observational Study Participant Information Sheets

Staff Version 4.1: 9th July 2015

Study title
A comparison in the clinical application, patient experience and health economics between independent nurse prescribing and patient group directions in sexual health services

Invitation and brief summary
We'd like to invite you to take part in a research study because you are a nurse who is using nurse prescribing and/ or patient group directions within the sexual health department. Joining the study is entirely up to you, before you decide we would like you to understand why the research is being done and what it would involve for you. The researcher will go through this information sheet with you, to help you decide whether or not you would like to take part and answer any questions you may have. We'd suggest this should take about 10 minutes. Please feel free to talk to others about the study if you wish.

Available evidence on how nurses' ability to independently deliver medicines affects services and patient experience is limited. This study aims to explore these issues in the context of sexual health clinics. This study involves mixture of methods to explore this topic from different perspectives. You are being invited to participate in Task 4: Observational Study exploring nurse-patient interactions during clinical consultations where medication is delivered. You have been invited because you can deliver medications independently while managing patients

What's involved?
If you agree to take part in this study, you are requested to allow the researcher to observe 5 of your consultations where medication is delivered. It is not possible to know which consultations will result in patients receiving medication, therefore you may be asked to participate in the consultations which may not be included in the study (i.e. if no medication was required). The consultation will be audio taped and the researcher will be taking notes. The content of the consultation will be compared alongside clinical and prescribing protocols and guidelines to explore if guidelines are adhered to during medication delivery.

What are the possible benefits of taking part?
There is no direct benefit but your help may allow us to have a deeper understanding of how nurses independently deliver medication in sexual health.

What are the possible disadvantages and risks of taking part?
Obtaining consent for patients to participation may mean that the consultation may take a little longer. As part of the observations, it may be found that medication was not appropriately or safely provided. In the unlikely event of this occurring the researcher will intervene at an appropriate point to ensure patient safety is maintained.

What if there is a problem?
Should you consider during the consultation that the patient is vulnerable (e.g. sexual assault, abuse, etc.) or they appear uncomfortable with the research please ask the researcher to terminate the observations.
If you have a concern about any aspect of this study, you should ask to speak to the researcher who will do their best to answer your questions. In the first instance please contact Adam Black (Researcher) on 07XXXXXXXXX or adam.black@kcl.ac.uk. Should you have any further concerns, please contact: Professor Christine Norton (Principle Investigator) by email: Christine.norton@kcl.ac.uk

If you have a complaint, you should talk to Adam Black who will do his best to answer your questions. If you remain unhappy, you may be able to make a formal complaint through the NHS

complaints procedure. Details can be obtained through the Patient Advisory Liaison Service [insert local details]

This study is sponsored by King's College London. The sponsor will at all times maintain adequate insurance in relation to the study independently. Kings College London, through its own professional indemnity (Clinical Trials) and no fault compensation.

What will happen if I don't want to carry on with the study?
Participation is entirely voluntary. Should you decide that you do not wish to participate, or later withdraw, you do not need to provide a rationale and you will not be penalised in any way.

Will my information be kept confidential?
Your participation will be treated confidentially. Your interview will have a study ID allocated to it, traceable only by the researcher. The device used to record the interview will encrypt the data. The audio recording will be transcribed verbatim and will be compared against the National Prescribing Centre's Prescribing Framework. Both the audio file and transcription will be securely stored on a Virtual Private Network at Imperial College Healthcare NHS Trust, which is accessible only by Adam Black and Professor Christine Norton. Responses from all participants will be combined for analysis and you will not be named in any reports or publications. All information which is collected during the course of the research will be kept confidential, in accordance with the Data Protection Act 1998. Should you wish feedback or a copy of your transcribed consultation(s) please contact Adam Black. The prescribing framework field notes will be scanned and stored securely on the VPN, hardcopies will be destroyed as confidential NHS waste.

What will happen to the results of this study?
The results of the study will be reviewed against other participants and undergo descriptive analysis, statistical testing and a health economics review. The data will be used to write up a PhD thesis and be disseminated in relevant professional journals and conferences.

Who is organising and funding the research?
The study is organised by Adam Black, a Consultant Nurse in Sexual Heath prior to undertaking a PhD fellowship. This study is funded through a Clinical Doctoral Research Fellowship by the National Institute of Health Research & Health Education England (NIHR/HEE). The study forms part of a PhD programme at the King's College London undertaken by Adam Black.

Who has reviewed this study?
All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by Wales 4 Research Ethics Committee, ref: 15/WA/0120. The study was also reviewed by the department's Research & Development prior to starting.

Further information and contact details
Specific advice about this research study: please contact Adam Black on 07XXXXXXXXX or by email at adam.black@kcl.ac.uk. Should you have any further concerns please contact the Principal Investigator at King's College London, Professor Christine Norton, by email: christine.norton@kcl.ac.uk

Advice as to whether they should participate: Should you require any independent advice on participating in research please speak to the nurse manager, the Research & Development team or the Patient Advisory Liaison Service.

Please keep for your records

Appendix Q. Observational study: Staff consent form

Trust Logo

Task 4 Staff Observational Study Consent Form
Version 4.1: 9th July 2015

Centre Number:

Study Number:

Participant Identification Number for this project:

CONSENT FORM

Title of Project: A comparison in the clinical application, patient experience and health economics between independent nurse prescribing and patient group directions in sexual health services:
Task 4 Observational Study: Staff

Name of Researcher: Adam Black

Please initial box

1. I confirm that I have read the information sheet dated 9th July 2015 (version 4.1) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my legal rights being affected. ☐
3. I understand that relevant sections of the medical notes and data collected during the study may be looked at by the researcher, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records. ☐
4. I give permission for my consultations to be observed and audio recorded, and understand the material will be used for research purposes. ☐
5. I am aware that if the research is not appropriate for specific presentations the observation will be terminated (e.g. sexual assault, vulnerable patient). ☐
6. I agree to take part in the above study. ☐

_____	_____	_____
Name of Participant	Date	Signature
_____	_____	_____
Name of Person taking consent	Date	Signature

When completed: 1 for participant; 1 for researcher site file; 1 (original) to be kept in medical notes.

Appendix R. Observational study: Patient participant information sheet (English version)

Task 4 Patient Observational Study Participant Information Sheets

Version 5.1: 9th July 2015

Title: Nurses independently delivering medication in sexual health

Invitation & summary: A research project is being undertaken in the clinic today, and you may be invited to participate. The study involves a researcher observing and audio-taping nurses' consultations. The purpose of the research is to gain a further understanding of the role of nurses in the delivery of medication in sexual health.

What's involved: If the nurse you see is included in the research, he/she will ask you at the start of the consultation if you are willing to have your consultation observed and audio-recorded. You do not need to do anything extra from a normal visit to the department. If you agree to having your consultation observed and audio-recorded, you will be asked to sign a consent form (attached). **Participation is completely voluntary.**

What are the possible benefits: There is no specific benefit to you, but it will help us better understand how nurses deliver medication independently.

What are the possible disadvantages: This may slightly increase the time you spend in the department.

What if there is a problem: Please speak to Adam Black (researcher) in the first instance on 07XXXXXXXXX or adam.black@kcl.ac.uk. If you have further concerns please contact Professor Christine Norton (Principle Investigator) by email: Christine.norton@kcl.ac.uk. If you remain unhappy, you may be able to make a formal complaint through the NHS complaints procedure. Details can be obtained through Patient Advisory Liaison Service [insert local details]. This study is sponsored by King's College London. The sponsor will at all times maintain adequate insurance in relation to the study independently. Kings College London, through its own professional indemnity (Clinical Trials) and no fault compensation.

What if I don't want to carry on with the study: You do not have to agree to your consultation being observed. The care you receive today will not be affected by a decision not to participate. If you later decide you would like to withdraw you can contact the researcher (details below) up to 48 hours after your visit. All information collected for research purposes during your visit will then be destroyed and not used in the study.

Will my information be kept confidential:
Your participation will be treated confidentially. Your interview will have a study ID allocated to it, traceable only by the researcher. The device used to record the interview will encrypt the data. The audio recording will be transcribed and compared against a national prescribing framework. Data will be securely stored on a Virtual Private Network at Imperial College Healthcare NHS Trust, accessible only by Adam Black and Professor Christine Norton. Responses from all participants will be combined for analysis. You will not be named in any reports or publications. All information which is collected during the course of the research will be kept confidential, in accordance with the Data Protection Act 1998. Should you wish a copy of your transcribed consultation please contact Adam Black.

What will happen to the results of the study:
The researcher will only analyse the information collected if medicines are provided. If medicines are not provided, the information will be destroyed. The results of the study will be reviewed against other participants and undergo descriptive analysis, statistical testing and a health economics review. The data will be used to write up a PhD thesis and be disseminated in relevant professional journals and conferences.

Who has reviewed this study: The study has been given a favourable opinion by an independent group of people called a Research Ethics Committee (Wales 4, Ref: 15/WA/0120).

Further contact: Researcher: Adam Black t: 07XXXXXXXXX e: adam.black@kcl.ac.uk
Further query Chief Investigator: Professor Christine Norton e: christine.norton@kcl.ac.uk

Further advice relating to participating in research or about your clinical care: nurse-in-charge or PALS (details above)

Please keep this information sheet for your own records

Appendix S. Observational study: Patient participant information sheet (Welsh version)

Taflen Wybodaeth i Gyfranogion am Dasg 4, Astudiaeth Arsylwi ar Gleifion

Fersiwn 5.1: 9fed Gorffennaf 2015

Teitl: Nyrsys yn darparu meddyginiaeth yn annibynnol ym maes iechyd rhywiol

Gwahoddiad a chrynodeb: Mae prosiect ymchwil yn mynd rhagddo yn y clinig heddiw, ac mae'n bosibl y cewch eich gwahodd i gymryd rhan. Yn ystod yr astudiaeth, bydd ymchwilydd yn arsylwi ar ymgynghoriadau nyrsys ac yn eu recordio (sain). Diben yr ymchwil yw dod i ddeall rôl nyrsys yn well wrth ddarparu meddyginiaethau ym maes iechyd rhywiol.

Beth y mae hyn yn galw amdano: Os bydd y nyrs y byddwch chi'n ei (g)weld wedi'i chynnwys/ei gynnwys yn yr ymchwil, fe fydd yn gofyn ichi ar ddechrau'r ymgynghoriad a ydych chi'n fodlon i'r ymchwilydd arsylwi ar eich ymgynghoriad a'i recordio. Nid oes angen ichi wneud unrhyw beth ychwanegol at ymweliad arferol â'r adran. Os byddwch chi'n cytuno i'r ymchwilydd arsylwi ar eich ymgynghoriad a'i recordio, fe fydd gofyn ichi lofnodi ffurflen gydsynio (wedi'i hatodi). **Byddwch chi'n cymryd rhan yn llwyr o'ch gwirfodd.**

Beth yw'r manteision posibl: Nid oes unrhyw fantais benodol i chi, ond fe fydd yn ein helpu ni i ddeall yn well sut mae nyrsys yn darparu meddyginiaethau'n annibynnol.

Beth yw'r anfanteision posibl: Mae'n bosibl y bydd hyn yn golygu y byddwch chi'n treulio ychydig yn fwy o amser yn yr adran.

Beth os oes yna broblem: Siaradwch ag Adam Black (ymchwilydd) yn y lle cyntaf ar 07XXXXXXXXX neu adam.black@kcl.ac.uk. Os oes gennych chi unrhyw bryderon pellach, yna cysylltwch â'r Athro Christine Norton (Pen Ymchwilydd) trwy e-bost: Christine.norton@kcl.ac.uk. Os byddwch chi'n dal i fod yn anhapus, mae'n bosibl y gallwch chi ddefnyddio gweithdrefn y GIG i wneud cwyn ffurfiol. Mae manylion i'w cael trwy'r Adran Gwynion ym Mwrdd Iechyd Prifysgol Caerdydd a'r Fro ffôn: 02920744095, e-bost: concerns@wales.nhs.uk, cyfeiriad: Adran Gwynion, Bwrdd Iechyd Prifysgol Caerdydd a'r Fro, Ysbyty Athrofaol Cymru, Parc y Mynydd Bychan, Caerdydd, CF14 4XW. Noddir yr astudiaeth hon gan King's College London. Bydd y noddwr, sef King's College London, bob amser yn cynnal yswiriant digonol yn annibynnol o ran yr astudiaeth, trwy ei yswiriant indemniad proffesiynol (Treialon Clinigol) a'i iawndal 'dim bai' ei hun.

Beth os na fydda' i eisiau bwrw ymlaen â'r astudiaeth: Nid oes yn rhaid ichi gytuno i'r ymchwilydd arsylwi ar eich ymgynghoriad. Ni fydd penderfynu peidio â chymryd rhan yn effeithio ar y gofal y byddwch chi'n ei dderbyn heddiw. Os byddwch chi'n penderfynu yn nes ymlaen eich bod chi eisiau tynnu yn ôl, gallwch chi gysylltu â'r ymchwilydd (manylion isod) hyd at 48 awr ar ôl eich ymweliad. Yna caiff yr holl wybodaeth a gasglwyd at ddibenion ymchwil yn ystod eich ymweliad ei dinistrio ac ni chaiff ei defnyddio yn yr astudiaeth.

A fydd fy ngwybodaeth yn cael ei chadw'n gyfrinachol:
Caiff y rhan y byddwch chi'n ei chwarae yn yr astudiaeth ei thrin yn gyfrinachol. Dyrennir ID astudiaeth i'ch cyfweliad, a dim ond yr ymchwilydd fydd yn gallu olrhain hwn. Bydd y dyfais a ddefnyddir i recordio'r cyfweliad yn amgryptio'r data. Caiff y recordiad ei drawsgrifio a'i gymharu â fframwaith rhagnodi cenedlaethol. Caiff y data eu storio ar Rith-rwydwaith Preifat yn Imperial College Healthcare NHS Trust, a dim ond Adam Black a'r Athro Christine Norton fydd yn gallu eu cyrchu. Caiff ymatebion oddi wrth bawb sy'n cymryd rhan eu cyfuno i'w dadansoddi. Ni fyddwch chi'n cael eich enwi mewn unrhyw adroddiadau neu gyhoeddiadau. Caiff yr holl wybodaeth a gesglir yn ystod yr ymchwil ei chadw'n gyfrinachol, yn unol â Deddf Diogelu Data 1998. Os byddwch chi eisiau copi o'r trawsgrifiad o'ch ymgynghoriad, yna cysylltwch ag Adam Black.

Beth fydd yn digwydd i ganlyniadau'r astudiaeth:
Dim ond pan ddarperir meddyginiaethau y bydd yr ymchwilydd yn dadansoddi'r wybodaeth a gesglir. Os na ddarperir meddyginiaethau, caiff yr wybodaeth ei dinistrio. Caiff canlyniadau'r

astudiaeth eu hadolygu yn erbyn cyfranogwyr eraill a byddan nhw'n destun dadansoddiad disgrifiadol, profion ystadegol ac adolygiad economeg iechyd. Caiff y data eu defnyddio i ysgrifennu thesis PhD a'u rhannu mewn cynadleddau a chyfnodolion proffesiynol.

Pwy sydd wedi adolygu'r astudiaeth hon: Mae grŵp annibynnol o bobl o'r enw Pwyllgor Moeseg Ymchwil *(Cymru 4, Cyf: 15/WA/0120) wedi edrych ar yr astudiaeth ac mae'n ffafriol ei farn arni.*

Cyswllt pellach: Ymchwilydd: Adam Black ffôn: 0XXXXXXXX e-bost: adam.black@kcl.ac.uk
Prif Ymchwilydd ar gyfer ymholiadau pellach: Yr Athro Christine Norton e-bost: christine.norton@kcl.ac.uk

Cyngor pellach ynglŷn â chymryd rhan mewn ymchwil neu ynglŷn â'ch gofal clinigol: y nyrs wrth y llyw neu'r Adran Gwynion (manylion uchod)

A fyddech cystal â chadw'r daflen wybodaeth hon i gyfeirio ati

Appendix T. Observational study: Patient consent form (English version)

Trust Logo

Task 4 Patient Observational Study Consent Forms
Version 5.1: 9th July 2015

Centre Number:

Study Number:

Participant Identification Number for this project:

CONSENT FORM

Title of Project: A comparison in the clinical application, patient experience and health economics between independent nurse prescribing and patient group directions in sexual health services:
Task 4 Observational Study: Patients

Name of Researcher: Adam Black

Please initial box

1. I confirm that I have read the information sheet dated 9th July 2015 (version 5.1) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care legal rights being affected. I am also aware that I can contact the researcher up to 48 hours after my visit to the clinic should I change my mind about taking part in the study, and that the research data collected during my consultation will be destroyed. ☐
3. I understand that relevant sections of my medical notes and data collected during the study may be looked at by the researcher, only where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records. ☐
4. I give permission for my consultations to be observed and audio recorded, and understand the material will be used for research purposes ☐
5. I agree to take part in the above study. ☐

_____	_____	_____
Name of Participant	Date	Signature
_____	_____	_____
Name of Person taking consent	Date	Signature

When completed: 1 for participant; 1 for researcher site file; 1 (original) to be kept in medical notes.

Appendix U. Observational study: Patient consent form (Welsh version)

GIG CYMRU NHS WALES | Bwrdd Iechyd Prifysgol Caerdydd a'r Fro | Cardiff and Vale University Health Board

Ffurflen Gydsynio Tasg 4, Astudiaeth Arsylwi ar Gleifion
Fersiwn 5.1: 9fed Gorffennaf 2015

Rhif Canolfan: 5

Rhif Astudiaeth:

Rhif Adnabod Cyfranogwr ar gyfer y prosiect hwn:

FFURFLEN GYDSYNIO

Teitl y Prosiect: Cymhariaeth rhwng nyrs yn rhagnodi presgripsiwn yn annibynnol a chyfarwyddiadau grŵp cleifion mewn gwasanaethau iechyd rhywiol o ran cymhwyso clinigol, profiad y claf ac economeg iechyd:
Tasg 4 Astudiaeth Arsylwi: Cleifion

Rhowch eich llythrennau blaen yn y blychau

Enw'r Ymchwilydd: Adam Black

1. Rwy'n cadarnhau fy mod wedi darllen y daflen wybodaeth ddyddiedig 9fed Gorffennaf 2015 (fersiwn 5.1) ar gyfer yr astudiaeth uchod. Rwyf wedi cael y cyfle i ystyried yr wybodaeth ac i ofyn cwestiynau, ac mae'r rhain wedi'u hateb yn foddhaol. ☐
2. Rwy'n deall mai o'm gwirfodd yr wyf yn cymryd rhan ac fy mod yn rhydd i dynnu yn ôl unrhyw adeg, heb roi unrhyw reswm, a heb i hynny effeithio ar fy hawliau cyfreithiol o ran gofal meddygol. Rwyf hefyd yn ymwybodol y gallaf gysylltu â'r ymchwilydd hyd at 48 ar ôl fy ymweliad â'r clinig os byddaf yn newid fy meddwl ynglŷn â chymryd rhan yn yr astudiaeth, ac y caiff y data ymchwil a gasglwyd yn ystod fy ymgynghoriad eu dinistrio. ☐
3. Rwy'n deall y gall yr ymchwilydd edrych ar adrannau perthnasol o fy nodiadau meddygol ac ar ddata a gesglir yn ystod yr astudiaeth, dim ond lle bo hynny'n berthnasol i'r rhan yr wyf ei chwarae yn yr ymchwil hon. Rwy'n caniatáu i'r unigolyn hwn gael gweld fy nghofnodion. ☐
4. Rwy'n caniatáu i'r ymchwilydd arsylwi ar fy ymgynghoriad a'i recordio (sain), ac rwy'n deall y caiff y deunydd ei ddefnyddio at ddibenion ymchwil ☐
5. Rwy'n cytuno i gymryd rhan yn yr astudiaeth uchod. ☐

_____	_____	_____
Enw'r Cyfranogwr	Dyddiad	Llofnod
_____	_____	_____
Enw'r Person sy'n cymryd y cydsyniad	Dyddiad	Llofnod

Ar ôl llenwi'r ffurflen: Rhoi 1 i'r cyfranogwr; rhoi 1 yn ffeil safle'r ymchwilydd; cadw 1 (y gwreiddiol) yn y nodiadau meddygol.

Appendix V. Observational study: Advertising poster

We are conducting nursing research in clinic today

- Participation is entirely **voluntary**
- This research explores how nurses deliver medications in sexual health.
- You may be asked if your consultation can be observed and audio-recorded by an experienced nurse
- If you decide you do not want to be part of the research, your care will **NOT** be affected in any way
- If you would like to participate but then change your mind, you can withdraw at any point up to 48 hours after your visit
    - Your identifiable information (e.g. your name) will not be recorded. You will not be identifiable in reports from the research

Version 3.1: 26th May 2015

If you would like more information please contact the researcher, Adam Black on oXXXXXXXXXX or adam.black@kcl.ac.uk

Appendix W. Research Ethics Committee Approval (28/05/2015)

Part of the research infrastructure for Wales funded by the National Institute for Social Care and Health Research, Welsh Government.
Yn rhan o seilwaith ymchwil Cymru a ariannir gan y Sefydliad Cenedlaethol ar gyfer Ymchwil Gofal Cymdeithasol ac Iechyd, Llywodraeth Cymru

NISCHR RES
Gwasanaeth Moeseg Ymchwil | Research Ethics Service

Wales REC 4
G1/G2 Croesnewydd Hall
Croesnewydd Road
Wrexham Technology Park
Wrexham LL13 7YP

Telephone : 01978 726377

E-mail : tracy.biggs@wales.nhs.uk

Website : www.nres.nhs.uk

28 May 2015

Professor Christine Norton
Room 2.25 James Clerk Maxwell Building
King's College London
57 Waterloo Road, London
SE1 8WA

Dear Professor Norton

Study title:	**A comparison in the clinical application, patient experience and health economics between independent nurse prescribing and patient group directions in sexual health services.**
REC reference:	**15/WA/0120**
IRAS project ID:	**148264**

Thank you for your letter of 26 May 2015, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information was considered by a Sub-Committee of the REC at a meeting held on 28 May 2015. A list of the Sub-Committee members is attached.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this favourable opinion letter. The expectation is that this information will be published for all studies that receive an ethical opinion but should you wish to provide a substitute contact point, wish to make a request to defer, or require further information, please contact the REC Manager, Mrs Tracy Biggs, Tracy.Biggs@Wales.nhs.uk. Under very limited circumstances (e.g. for student research which has received an unfavourable opinion), it may be possible to grant an exemption to the publication of the study.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Appendix X. Research Ethics Committee Non-substantial Amendment Approval (21/09/2015)

Part of the research infrastructure for Wales funded by the National Institute for Social Care and Health Research, Welsh Government.
Yn rhan o seilwaith ymchwil Cymru a ariannir gan y Sefydliad Cenedlaethol ar gyfer Ymchwil Gofal Cymdeithasol ac Iechyd, Llywodraeth Cymru

NISCHR RES
Gwasanaeth Moeseg Ymchwil | Research Ethics Service

Wales REC 4
G1/G2 Croesnewydd Hall
Croesnewydd Road
Wrexham Technology Park
Wrexham LL13 7YP

Telephone : 01978 726377

E-mail : tracy.biggs@wales.nhs.uk

Website : www.nres.nhs.uk

21 September 2015

Professor Christine Norton
Room 2.25 James Clerk Maxwell Building
King's College London
57 Waterloo Road, London
SE1 8WA

Dear Professor Norton

Study title:	**A comparison in the clinical application, patient experience and health economics between independent nurse prescribing and patient group directions in sexual health services.**
REC reference:	**15/WA/0120**
Amendment number:	**1**
Amendment date:	**11 August 2015**
IRAS project ID:	**148264**

Thank you for your letter of 11 August 2015, notifying the Committee of the above amendment.

It is noted that the amendment has been classified and approved by the sponsor as non-substantial. The amendment has been provided as notification to the REC as there have been some clarifications added after a review by the REC, NIHR CSP and Information Governance/ Caldecott Guardian. The changes are in respect of clarifying the consent process for patients in the observation aspect and clarifying data processing and handling. Information regarding information security has been added to the consent form.

The Committee does not consider this to be a "substantial amendment" as defined in the Standard Operating Procedures for Research Ethics Committees. The amendment does not therefore require an ethical opinion from the Committee and may be implemented immediately, provided that it does not affect the approval for the research given by the R&D office for the relevant NHS care organisation.

Documents received

The documents received were as follows:

Document	*Version*	*Date*
Participant Information Sheets (task 1)	V4.2	09 July 2015
Participant Information Sheets (task 2)	V6.1	09 July 2015
Participant Information Sheets (task 3)	V8.1	09 July 2015
Participant Information Sheets (task 4 staff)	V4.1	09 July 2015
Participant Information Sheets (task 4 patient)	V5.1	09 July 2015
Participant Information Sheets (task 5)	V4.1	09 July 2015
Consent form (task 1)	V4.2	09 July 2015

Appendix Y. Research Ethics Committee Substantial Amendment Approval (21/03/2016)

Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

Gwasanaeth Moeseg Ymchwil
Research Ethics Service

Ariennir gan Lywodraeth Cymru
Funded by Welsh Government

Wales REC 4
G1/G2 Croesnewydd Hall
Croesnewydd Road
Wrexham Technology Park
Wrexham LL13 7YP

Telephone : 01978 726377
E-mail : tracy.biggs@wales.nhs.uk
Website : www.hra.nhs.uk

21 March 2016 (reissued)

Professor Christine Norton
Room 2.25 James Clerk Maxwell Building
King's College London
57 Waterloo Road, London
SE1 8WA

Dear Professor Norton

Study title:	**A comparison in the clinical application, patient experience and health economics between independent nurse prescribing and patient group directions in sexual health services.**
REC reference:	**15/WA/0120**
Amendment number:	**6.2**
Amendment date:	**01 February 2016**
IRAS project ID:	**148264**

The above amendment was reviewed at the meeting of the Sub-Committee held on 11 March 2016.

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

The Committee noted the study amendment to source clinical records using a standard audit format.

Approved documents

The documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
Notice of Substantial Amendment (non-CTIMP)	6.2	01 February 2016
Participant consent form [Task 3A]	8.2	01 February 2016
Participant information sheet (PIS) [Task 3A]	8.2	01 February 2016
Research protocol or project proposal	6.2	01 February 2016

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

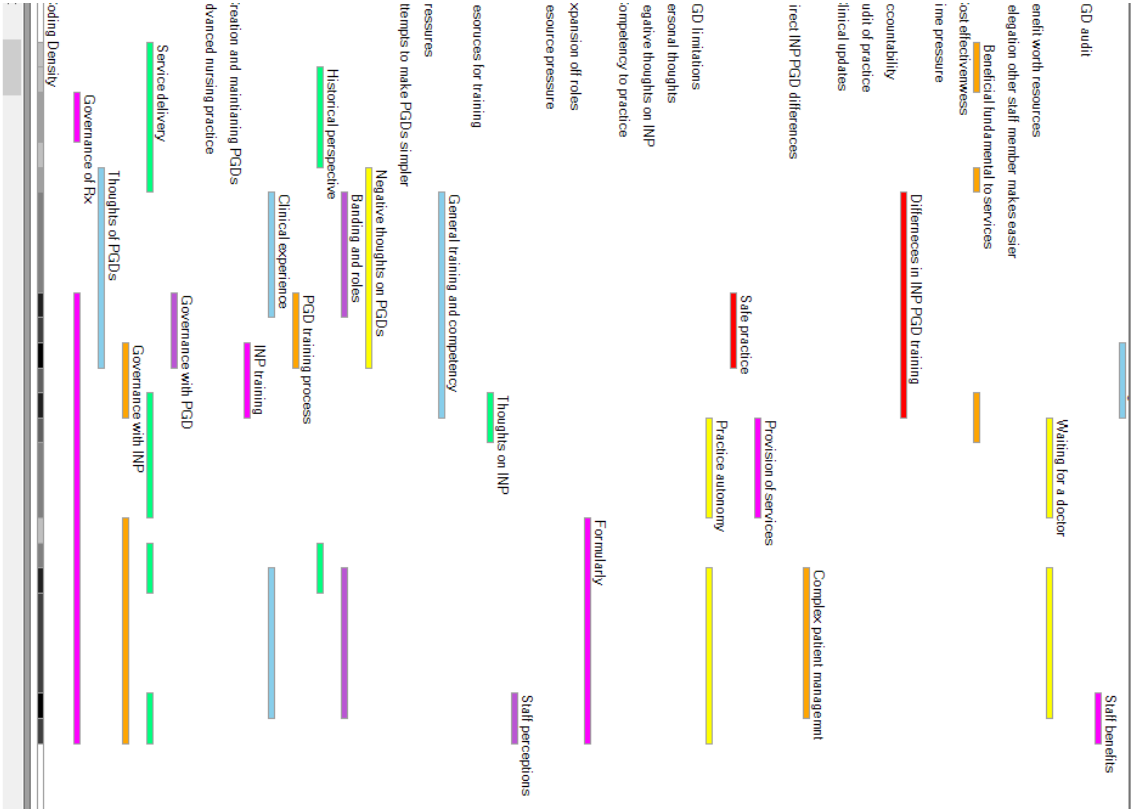
R&D approval

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

Appendix Z. Staff interviews: Example of transcript coding

have problems because nurses are able to independently deliver medications within their clinics?

So I think nurses being able to issue medication is hugely beneficial in terms of the service that we provide. We've had nurse practitioners working in sexual health here since 1996. And I started here in 97, and we had group protocols within which we used to issue medication, but we subsequently discovered that legality of those may or may not have completely ideal. And that led on to obviously PGDs and then on to non-medical prescribing. I think it is great that...I don't think...I don't know which way round to start this. I think it is great that nurses are able to do this. I think some of the challenges are that the most junior nurses issue against a patient group direction, so our Band 5s use PGDs to issue or administer Hepatitis vaccinations, emergency contraception and to treat contacts of things like NSU and gonorrhoea and stuff. The problem is they don't necessarily get any in-depth pharmacology, pharmacokinetics, pharmacodynamics in relation to administering those. So the most junior people are administering medication, and we assess them robustly in terms of making sure they are safe and effective in what they do, but they don't necessarily have the theoretical underpinnings for that. Whereas our non-medical prescriber...our Band...our nurse practitioners are all non-medical prescribers, or are working towards being a non-medical prescriber and they get that theoretical component to it...so...but...I think for me personally it's the thing that has completely opened up practice, because it means you're not relying on having to hang around a door, waiting for a doctor, either to prescribe a vaccine or...to...you know...so that you can manage a...your... patient independently if you've got...you know if you're a non-medical...if you're...a nurse practitioner and you're seeing your patient you're able to treat them. And I think the other thing with that is that is if you've...we have been very clear about not having a very tight formulary, so I know that historically within the Trust they've wanted to have like a really, really tight formulary saying that non-medical prescribers can prescribe A or B or C. And we resisted that and kept it quite broad, which is really helpful when you've got a nurse practitioner who then goes and sees a patient and they've got something that you wouldn't normally treat, and then they get a medical review, and the doctor will go "oh, they need some Augmentin". And then the nurse practitioner, who is a non-medical prescriber, can then actually just do a script for Augmentin and doesn't have to rely on someone else doing that script. Again, it sort of frees up their practice, and it enables them to sort of develop their practice as well, because it's not constrained by you can only use those things. Sorry, I'm not sure if that answers your question?



Appendix AA. Nurse questionnaire: Participants' attitudes to impact independent access to medication has on their clinical practice

Question		INP (n=26) PGD (n=35)	Strongly agree		Agree		Neutral		Disagree		Strongly Disagree		Response rate	
			n	%	n	%	n	%	n	%	n	%	n	%
1	Being able to independently deliver medication makes my clinical role easier	INP	21	80.8	4	15.4	0	0.0	0	0.0	0	0.0	25	96.2
		PGD	28	80.0	7	20.0	0	0.0	0	0.0	0	0.0	35	100.0
		Total	49	80.3	11	18.0	0	0.0	0	0.0	0	0.0	60	98.4
2	Being able to independently deliver medication is essential for my current role	INP	13	50.0	10	38.5	1	3.8	1	3.8	0	0.0	25	96.2
		PGD	24	68.6	9	25.7	2	5.7	0	0.0	0	0.0	35	100.0
		Total	37	60.7	19	31.1	3	4.9	1	1.6	0	0.0	60	98.4
3	I feel my skills in prescribing are being used effectively	INP	18	69.2	6	23.1	1	3.8	0	0.0	0	0.0	25	96.2
		PGD	13	37.1	16	45.7	2	5.7	1	2.9	0	0.0	32	91.4
		Total	31	50.8	22	36.1	3	4.9	1	1.6	0	0.0	57	93.4
4	I believe patients obtain a better experience because I deliver medications independently	INP	17	65.4	7	26.9	0	0.0	1	3.8	0	0.0	25	96.2
		PGD	25	71.4	10	28.6	0	0.0	0	0.0	0	0.0	35	100.0
		Total	42	68.9	17	27.9	0	0.0	1	1.6	0	0.0	60	98.4
5	I am confident in my ability to independently deliver medication	INP	14	53.8	11	42.3	0	0.0	0	0.0	0	0.0	25	96.2
		PGD	21	60.0	9	25.7	5	14.3	0	0.0	0	0.0	35	100.0
		Total	35	57.4	20	32.8	5	8.2	0	0.0	0	0.0	60	98.4
6	Confidence in my clinical practice has increased since I have been able to deliver medication independently	INP	14	53.8	8	30.8	3	11.5	0	0.0	0	0.0	25	96.2
		PGD	14	40.0	16	45.7	5	14.3	0	0.0	0	0.0	35	100.0
		Total	28	45.9	24	39.3	8	13.1	0	0.0	0	0.0	60	98.4
7	Training enabling me to deliver medication independently was adequate	INP	10	38.5	11	42.3	3	11.5	1	3.8	0	0.0	25	96.2
		PGD	13	37.1	13	37.1	6	17.1	3	8.6	0	0.0	35	100.0
		Total	23	37.7	24	39.3	9	14.8	4	6.6	0	0.0	60	98.4
8	I am supported in meeting my CPD needs to deliver medicines independently	INP	4	15.4	13	50.0	4	15.4	4	15.4	0	0.0	25	96.2
		PGD	10	28.6	17	48.6	7	20.0	1	2.9	0	0.0	35	100.0
		Total	14	23	30	49.2	11	18.0	5	8.2	0	0.0	60	98.4

Question		INP (n=26) PGD (n=35)	Strongly agree		Agree		Neutral		Disagree		Strongly Disagree		Response rate	
			n	%	n	%	n	%	n	%	n	%	n	%
9	Independent medicine delivery has resulted in me feeling more satisfied in my role	INP	14	53.8	7	26.9	4	15.4	0	0.0	0	0.0	25	96.2
		PGD	17	48.6	13	37.1	4	11.4	0	0.0	0	0.0	34	97.1
		Total	31	50.8	20	32.8	8	13.1	0	0.0	0	0.0	59	96.7
10	I would recommend nurse prescribing / PGD to a department not using it	INP	18	69.2	5	19.2	1	3.8	1	3.8	0	0.0	25	96.2
		PGD	21	60.0	12	34.3	1	2.9	1	2.9	0	0.0	35	100.0
		Total	39	63.9	17	27.9	2	3.3	2	3.3	0	0.0	60	98.4
11	Overall I feel the effort required in training to deliver medications independently was worthwhile	INP	18	69.2	5	19.2	2	7.7	0	0.0	0	0.0	25	96.2
		PGD	19	54.3	12	34.3	4	11.4	0	0.0	0	0.0	35	100.0
		Total	37	60.7	17	27.9	6	9.8	0	0.0	0	0.0	60	98.4
Grand total (from potential 671 responses):			366	54.5	221	32.9	55	8.2	14	2.1	0	0.0	656	97.8

INP= independent nurse prescribing, PGD= patient group directions, CPD = continuing professional development

Appendix BB. Clinical diary: Detailed diary activity by site

Diary entries		Site 1				Site 2				Site 3			Site 4				Site 5				Total			
		INP (n=424)		PGD (n=82)		INP (n=16)		PGD (n=40)		INP (n=0)	PGD (n=33)		INP (n=236)		PGD (n=107)		INP (n=61)		PGD (n=331)		INP (n=737)		PGD (n=593)	
		n	%	n	%	n	%	n	%		n	%	n	%	n	%	n	%	n	%	n	%	n	%
Presentation	New	317	74.8	49	59.8	6	37.5	25	62.5		23	69.7	154	65.3	82	76.6	35	57.4	115	34.7	512	69.5	294	49.6
	Follow-up	105	24.8	33	40.2	10	62.5	15	37.5		10	30.3	79	33.5	21	19.6	26	42.6	201	60.7	220	29.9	280	47.2
	Both	0	0.0	0	0.0	0	0.0	0	0.0		0	0.0	0	0.0	0	0.0	0	0.0	1	0.3	0	0.0	1	0.2
	Missing	2	0.5	0	0.0	0	0.0	0	0.0		0	0.0	3	1.3	4	3.7	0	0.0	14	4.2	5	0.7	18	3.0
Medications given?	Med given	267	63.0	50	61.0	9	56.3	25	62.5		18	54.5	148	62.7	69	64.5	36	59.0	186	56.2	460	62.4	348	58.7
	No meds	143	33.7	32	39.0	7	43.8	15	37.5		15	45.5	87	36.9	38	35.5	24	39.3	132	39.9	261	35.4	232	39.1
	Missing	14	3.3	0	0.0	0	0.0	0	0.0		0	0.0	1	0.4	0	0.0	1	1.6	13	3.9	16	2.2	13	2.2
Advice sought?	Advice sought	27	6.4	18	22.0	0	0.0	7	17.5		0	0.0	44	18.6	26	24.3	4	6.6	31	9.4	75	10.2	82	13.8
	No advice Sought	324	76.4	57	69.5	12	75.0	19	47.5		29	87.9	191	80.9	70	65.4	53	86.9	276	83.4	580	78.7	451	76.1
	Missing	73	17.2	7	8.5	4	25.0	14	35.0		4	12.1	1	0.4	11	10.3	4	6.6	24	7.3	82	11.1	60	10.1
Type of advice?	Clinical	9	33.3	11	61.1	0	0.0	0	0		0	0.0	25	56.8	5	19.2	4	100	4	12.9	38	50.7	20	24.4
	Medicine	2	7.4	5	27.8	0	0.0	0	0		0	0.0	10	22.7	4	15.4	0	0.0	12	38.7	12	16.0	21	25.6
	Both	6	22.2	0	0.0	0	0.0	0	0		0	0.0	7	15.9	10	38.5	0	0.0	2	6.5	13	17.3	12	14.6
	Missing	10	37.0	2	11.1	0	0.0	7	100		0	0.0	2	4.5	7	26.9	0	0.0	13	41.9	12	16.0	29	35.4
Advice obtained from	Doctor	11	40.7	6	33.3	0	0.0	7	100		0	0.0	29	65.9	23	88.5	2	50.0	22	71.0	42	56.0	60	73.2
	Nurse	1	3.7	2	11.1	0	0.0	0	0		0	0.0	2	4.5	1	3.8	0	0.0	3	9.7	3	4.0	6	7.3
	Pharmacist	1	3.7	0	0.0	0	0.0	0	0		0	0.0	4	9.1	0	0.0	0	0.0	1	3.2	5	6.7	1	1.2
	Health Adviser	2	7.4	0	0.0	0	0.0	0	0		0	0.0	0	0.0	1	3.8	0	0.0	2	6.5	2	2.7	3	3.7
	Missing	12	44.4	10	55.6	0	0.0	0	0		0	0.0	9	20.5	1	3.8	2	50.0	3	9.7	23	30.7	12	14.6
Medications given (from above)		267	63.0	50	61.0	9	56.3	25	62.5		18	54.5	148	62.7	69	64.5	36	59.0	186	56.2	460	62.4	348	58.7

Diary entries		Site 1				Site 2				Site 3			Site 4				Site 5				Total			
		INP (n=424)		PGD (n=82)		INP (n=16)		PGD (n=40)		INP (n=0)	PGD (n=33)		INP (n=236)		PGD (n=107)		INP (n=61)		PGD (n=331)		INP (n=737)		PGD (n=593)	
		n	%	n	%	n	%	n	%		n	%	n	%	n	%	n	%	n	%	n	%	n	%
Medication delivered?	Independently	253	94.8	30	60	8	88.9	10	40		10	55.6	126	85.1	39	56.5	32	88.9	151	81.2	419	91.1	240	69.0
	Rx: Doctor	5	1.9	12	24	1	11.1	9	36		7	38.9	21	14.2	25	36.2	2	5.6	27	14.5	29	6.3	80	23.0
	Rx: Nurse	2	0.7	8	16	0	0.0	0	0		0	0.0	0	0.0	1	1.4	0	0.0	1	0.5	2	0.4	10	2.9
	Rx: Pharmacist	2	0.7	0	0	0	0.0	0	0		0	0.0	1	0.7	3	4.3	0	0.0	0	0.0	3	0.7	3	0.9
	Rx: Health Adviser	2	0.7	0	0	0	0.0	0	0		0	0.0	0	0.0	1	1.4	0	0.0	0	0.0	2	0.4	1	0.3
	Rx: Missing	3	1.1	0	0	0	0.0	6	24		1	5.6	0	0.0	0	0.0	2	5.6	7	3.8	5	1.1	14	4.0
	No PGD			4	8			1	4		1	5.5			5	7.2			19	10.2			30	8.6

INP = independent nurse prescribing, PGDs = patient group directions, Rx: prescription from, No PGD: no PGD available to cover medication and/ or patient presentation

Appendix CC. Clinical notes review: Breakdown of nurses' procedural and diagnostic activity

Table 0-1 Procedural management of patients

Procedural	INP (n=743)				PGD (n=939)				Total (n=1682)	
	Med (n=399)		No med (n=344)		Med (n=480)		No med (n=459)			
	n	%	n	%	n	%	n	%	n	%
Asymptomatic screening	76	19.0	156	45.3	129	26.9	262	57.1	623	37.0
Symptomatic screen	106	26.6	44	12.8	102	21.3	37	8.1	289	17.2
Receiving results of tests	37	9.3	23	6.7	60	12.5	57	12.4	177	10.5
Vaccine	24	6.0	0	0.0	80	16.7	0	0.0	104	6.2
Health Adviser support	7	1.8	15	4.4	35	7.3	38	8.3	95	5.6
Contraception: maintain	43	10.8	0	0.0	47	9.8	0	0.0	90	5.4
Contraception: change	38	9.5	9	2.6	31	6.5	3	0.7	81	4.8
Contraception: new	40	10.0	0	0.0	35	7.3	1	0.2	76	4.5
Contraception: advice only	14	3.5	25	7.3	12	2.5	19	4.1	70	4.2
Termination of pregnancy	24	6.0	14	4.1	9	1.9	8	1.7	55	3.3
Emergency contraception	14	3.5	0	0.0	28	5.8	0	0.0	42	2.5
Safeguarding	8	2.0	10	2.9	10	2.1	6	1.3	34	2.0
Test of cure	3	0.8	6	1.7	5	1.0	20	4.4	34	2.0
Specialist follow-up	1	0.3	16	4.7	7	1.5	5	1.0	29	1.7
HIV Test only	1	0.3	7	2.0	0	0.0	9	2.0	17	1.0
Advice only	0	0.0	4	1.2	0	0.0	5	1.1	9	0.5
Cervical smear	0	0.0	3	0.9	1	0.2	4	0.9	8	0.5
HIV post exposure prophylaxis	3	0.8	0	0.0	1	0.2	1	0.2	5	0.3

INP= independent nurse prescribing, PGD= patient group directions, med= medication given, no med= no medication given, HIV = human immunodeficiency virus

Table 0-2 Diagnoses managed by nurses

Diagnoses	INP (n=743)				PGD (n=939)				Total (n=1682)	
	Med (n=399)		No med (n=344)		Med (n=480)		No med (n=459)			
	n	%	n	%	n	%	n	%	n	%
Chlamydia	53	13.3	12	3.5	69	14.4	20	4.4	154	9.2
Genital warts	38	9.5	3	0.9	39	8.1	1	0.2	81	4.8
Gonorrhoea	22	5.5	3	0.9	49	10.2	7	1.5	81	4.8
Contact chlamydia	33	8.3	0	0.0	39	8.1	0	0.0	72	4.3
Non-specific urethritis (NSU)	24	6.0	0	0.0	23	4.8	0	0.0	47	2.8
Bacterial vaginosis	21	5.3	1	0.3	21	4.4	2	0.4	45	2.7
Vulval-vaginal candidiasis	23	5.8	0	0.0	20	4.2	2	0.4	45	2.7
Contact gonorrhoea	12	3.0	2	0.6	25	5.2	3	0.7	42	2.5
Herpes	14	3.5	3	0.9	8	1.7	1	0.2	26	1.5
Other/ unknown	8	2.0	3	0.9	4	0.8	4	0.9	19	1.1
Dermatoses	4	1.0	5	1.5	9	1.9	0	0.0	18	1.1
Balanitis	5	1.3	2	0.6	9	1.9	1	0.2	17	1.0
Contact of NSU, PID or TV	8	2.0	0	0.0	9	1.9	0	0.0	17	1.0
Pelvic Inflammatory Disease (PID)	6	1.5	1	0.3	7	1.5	0	0.0	14	0.8
Epididymo-orchitis	6	1.5	0	0.0	4	0.8	1	0.2	11	0.7
Contact of syphilis	1	0.3	0	0.0	6	1.3	2	0.4	9	0.5
Urinary tract infection	4	1.0	1	0.3	4	0.8	0	0.0	9	0.5
Contact of HIV	0	0.0	3	0.9	2	0.4	1	0.2	6	0.4
Proctitis	4	1.0	0	0.0	1	0.2	0	0.0	5	0.3
Syphilis	1	0.3	0	0.0	4	0.8	0	0.0	5	0.3
Cervicitis	2	0.5	0	0.0	2	0.4	0	0.0	4	0.2
Lymphogranuloma venereum	1	0.3	0	0.0	2	0.4	0	0.0	3	0.2
Molloscum contagiosum	2	0.5	0	0.0	1	0.2	0	0.0	3	0.2
Trichomoniasis vaginalis (TV)	0	0.0	0	0.0	2	0.4	1	0.2	3	0.2
Hepatitis B	0	0.0	1	0.3	0	0.0	1	0.2	2	0.1
Human Immuno-deficiency Virus (HIV)	0	0.0	1	0.3	0	0.0	1	0.2	2	0.1
Hepatitis C	0	0.0	0	0.0	0	0.0	1	0.2	1	0.1

INP= independent nurse prescribing, PGD= patient group directions, med= medication given, no med= no medication given

Appendix DD. Clinical notes review: Specific medications delivered by INPs and PGD users

Specific drug delivered by INP & PGD (number of products)	INP (n=620)		PGD (n=737)		Total (n=1357)	
	n	%	n	%	n	%
Antibiotic (n=15)	203	32.7	283	38.4	486	35.8
Azithromycin	107	17.3	124	16.8	231	17.0
Benzathine penicillin G	2	0.3	10	1.4	12	0.9
Cefixime	1	0.2	2	0.3	3	0.2
Ceftriaxone	25	4.0	57	7.7	82	6.0
Ciprofloxacin	1	0.2	0	0.0	1	0.1
Co-amoxiclav	1	0.2	0	0.0	1	0.1
Doxycycline	26	4.2	50	6.8	76	5.6
Erythromycin	0	0.0	1	0.1	1	0.1
Flucloxacillin	2	0.3	1	0.1	3	0.2
Metronidazole	26	4.2	31	4.2	57	4.2
Nitrofurantoin	2	0.3	0	0.0	2	0.1
Ofloxacin	7	1.1	3	0.4	10	0.7
Procaine penicillin	0	0.0	1	0.1	1	0.1
Spectinomycin	2	0.3	0	0.0	2	0.1
Trimethoprim	1	0.2	3	0.4	4	0.3
Anaesthetics (n=2)	76	12.3	80	10.9	156	11.5
Lidocaine	75	12.1	71	9.6	146	10.8
Xylocaine®	0	0.0	9	1.2	9	0.7
Wart treatments (n=4)	56	9.0	60	8.1	116	8.5
Cryotherapy	35	5.6	39	5.3	74	5.5
Imiquimod	4	0.6	12	1.6	16	1.2
Podophyllotoxin	14	2.3	8	1.1	22	1.6
Trichloracetic acid	3	0.5	1	0.1	4	0.3
Vaccinations (n=3)	27	4.4	88	11.9	115	8.5
Hepatitis A vaccine	2	0.3	9	1.2	11	0.8
Hepatitis B vaccine	16	2.6	66	9.0	82	6.0
Twinrix (Hepatitis A&B) vaccine	9	1.5	13	1.8	22	1.6
Short acting contraception (pills, patch, ring: n=8)	59	9.5	54	7.3	113	8.3
Cerazette®/ Cerelle®/ Zelleta®	15	2.4	15	2.0	30	2.2
Cilest®	2	0.3	6	0.8	8	0.6
Evra (3M) ®	2	0.3	1	0.1	3	0.2
Femodette®/ Millinette 20®	0	0.0	2	0.3	2	0.1
Gedarel®	2	0.3	2	0.3	4	0.3
Microgynon®/ Rigivedon®	35	5.6	27	3.7	62	4.6
Micronor®	2	0.3	1	0.1	3	0.2
Nuvaring®	1	0.2	0	0.0	1	0.1
Long-Active Reversible Contraception (n=3)	52	8.4	53	7.2	105	7.7
DepoProvera®	9	1.5	16	2.2	25	1.8

Specific drug delivered by INP & PGD (number of products)	INP (n=620)		PGD (n=737)		Total (n=1357)	
	n	%	n	%	n	%
Intra-uterine device/ system	10	1.6	15	2.0	25	1.8
Nexplanon®	33	5.3	22	3.0	55	4.1
Antifungal (n=4)	49	7.9	42	5.7	91	6.7
Canesten HC®	0	0.0	5	0.7	5	0.4
Clotrimazole	40	6.5	29	3.9	69	5.1
Fluconazole	9	1.5	8	1.1	17	1.3
Termination of pregnancy regimens (excluding azithromycin: n=4)	30	4.8	11	1.5	41	3.0
Anti-D immunoglobulin	3	0.5	1	0.1	4	0.3
Cyclizine	3	0.5	0	0.0	3	0.2
Mifepristone	8	1.3	5	0.7	13	1.0
Misoprostol	15	2.4	5	0.7	20	1.5
Ondanstron	1	0.2	0	0.0	1	0.1
Emergency contraception (n=2)	14	2.3	26	3.5	40	2.9
Levonorgestrel	12	1.9	23	3.1	35	2.6
Uilpristal Acetate	2	0.3	3	0.4	5	0.4
Topical creams (n=10)	11	1.8	24	3.3	35	2.6
Aqueous Cream	0	0.0	4	0.5	4	0.3
Fusidic Acid	1	0.2	0	0.0	1	0.1
Instilligel®	3	0.5	10	1.4	13	1.0
Daktacort®	0	0.0	3	0.4	3	0.2
Dermol 500®	2	0.3	1	0.1	3	0.2
Diprobase®	2	0.3	4	0.5	6	0.4
Eumovate®	0	0.0	1	0.1	1	0.1
Hydramol	1	0.2	0	0.0	1	0.1
Hydrocortisone	0	0.0	1	0.1	1	0.1
Permethrin®	2	0.3	0	0.0	2	0.1
Antiviral (n=1)	14	2.3	8	1.1	22	1.6
Aciclovir	14	2.3	8	1.1	22	1.6
HIV anti-retroviral (n=4)	14	2.3	4	0.5	18	1.3
Atripla	1	0.2	0	0.0	1	0.1
Raltegravir	6	1.0	2	0.3	8	0.6
Triumeq	1	0.2	0	0.0	1	0.1
Truvada	6	1.0	2	0.3	8	0.6
Erectile dysfunction treatments (n=4)	10	1.6	1	0.1	12	0.9
Alprostadil	6	1.0	1	0.1	7	0.5
Caverjet®	1	0.2	0	0.0	1	0.1
Sildenafil	1	0.2	0	0.0	1	0.1
Tadalafil	3	0.5	0	0.0	3	0.2
Non-steroidal anti-inflammatory (n=2)	1	0.2	1	0.1	2	0.1
Ibuprofen	0	0.0	1	0.1	1	0.1
Mefeanic acid	1	0.2	0	0.0	1	0.1

INP= independent nurse prescribing, PGD= patient group directions, med= medication given, no med= no medication given

Appendix EE. Clinical notes review: Specific medications prescribed by doctors for INPs and PGD users

Drug groups prescribed by doctor for INP & PGD	INP (n=81)		Can INP provide?	PGD (n=225)		Can PGD provide?
	n	%		n	%	
Antiviral (n=1)	0	0.0		3	1.3	
Aciclovir	0	0.0	Yes	3	1.3	Yes
Antibiotic (n=11)	27	32.5		89	39.5	
Azithromycin*	17	20.5	Yes	26	11.6	Yes
Benzathine penicillin G	1	1.2	Yes	10	4.4	No
Cefixime	0	0.0	Yes	1	0.4	Yes
Ceftriaxone	3	3.6	Yes	16	7.1	Yes
Co-amoxiclav	1	1.2	Yes	0	0.0	No
Doxycycline	2	2.4	Yes	22	9.8	Yes
Erythromycin	0	0.0	Yes	1	0.4	No
Metronidazole	2	2.4	Yes	8	3.6	Yes
Ofloxacin	1	1.2	Yes	2	0.9	No
Procaine penicillin	0	0.0	Yes	1	0.4	No
Trimethoprim	0	0.0	Yes	2	0.9	No
HIV antiretroviral (n=2)	4	4.8		4	1.8	
Raltegravir	2	2.4	Yes	2	0.9	No
Truvada	2	2.4	Yes	2	0.9	No
Antifungal (n=3)	4	4.8		13	5.7	
Canesten HC	0	0.0	Yes	5	2.2	No
Clotrimazole	3	3.6	Yes	5	2.2	Yes
Fluconazole	1	1.2	Yes	3	1.3	Yes
Topical creams (n=4)	0	0.0		6	2.5	
Daktacort	0	0.0	Yes	3	1.3	No
Dermol 500	0	0.0	Yes	1	0.4	No
Diprobase	0	0.0	Yes	1	0.4	No
Eumovate	0	0.0	Yes	1	0.4	No
Termination of pregnancy regimens (excluding azithromycin; n=7)	29	34.9		12	5.2	
Anti-D immunoglobulin*	3	3.6	Yes	1	0.4	No
Antibiotic cover*	1	1.2	Yes	0	0.0	No
Cyclizine*	1	1.2	Yes	0	0.0	No
Mifepristone*	8	9.6	No	5	2.2	No
Misoprostol*	15	18.1	No	5	2.2	No
Ondanstron*	1	1.2	Yes	0	0.0	No
Other	0	0.0	Yes	1	0.4	No
Anaesthetics (n=1)	6	7.2		13	5.8	
Lidocaine	6	7.2	Yes	13	5.8	Yes
Short acting contraception (pills n=6)	3	3.6		22	9.7	
Cerazette®/ Cerelle®	1	1.2	Yes	4	1.8	Yes

Drug groups prescribed by doctor for INP & PGD	INP (n=81)		Can INP provide?	PGD (n=225)		Can PGD provide?
	n	%		n	%	
Cilest®	0	0.0	Yes	3	1.3	Yes
Femodette®/ Millinette 20®	0	0.0	Yes	1	0.4	Yes
Gedarel®	1	1.2	Yes	2	0.9	Yes
Microgynon®/ Rigivedon®	0	0.0	Yes	12	5.3	Yes
Micronor®	1	1.2	Yes	0	0.0	Yes
Wart treatments (n=5)	2	2.4		17	7.4	
Condyline®	0	0.0	Yes	1	0.4	Yes
Cryotherapy	1	1.2	Yes	10	4.4	Yes
Imiquimod	0	0.0	Yes	4	1.8	Yes
Podophyllotoxin	1	1.2	Yes	1	0.4	Yes
Trichloracetic acid	0	0.0	Yes	1	0.4	Yes
Long-Active Reversible Contraception (n=2)	1	1.2		5	2.2	
DepoProvera®	0	0.0	Yes	4	1.8	Yes
Intra-uterine device/ system	1	1.2	Yes	1	0.4	Yes
Emergency contraception (n=2)	0	0.0		8	3.5	
Levonorgestrel	0	0.0	Yes	7	3.1	Yes
Uilpristal Acetate	0	0.0	Yes	1	0.4	Yes
Vaccinations (n=3)	6	7.2		33	14.7	
Hepatitis A vaccine	0	0.0	Yes	2	0.9	Yes
Hepatitis B vaccine	4	4.8	Yes	23	10.2	Yes
Twinrix (Hep A&B)	2	2.4	Yes	8	3.6	Yes
Non-steroidal anti-inflammtory (n=1)	1	1.2		0	0.0	
Analgesia cover*	1	1.2	Yes	0	0.0	No

**Included in termination of pregnancy drug regimens, mifepristone and misoprostol must be prescribed by a doctor. INP= independent nurse prescribing, PGD= patient group directions*

Appendix FF. Clinical notes review: Medication safety assessments based on risk assessments

Condition	Medication delivered	Frequency		BNF safety comments for specific medical/ medication consideration	Appropriate use?
		INP	PGD		
Pregnancy (n=10)	Azithromycin	1	0	Use only if adequate alternatives not available	✓
	Ceftriaxone	1	0	Use if benefits outweigh risks; not known to be harmful in animal studies	✓
	Clotrimazole	1	2	Pregnant women need longer duration of treatment; oral antifungal treatment should be avoided. Topically minimal absorption from skin, not known to be harmful	✓
	Cryotherapy	4	0	No data in British National Formulary	✓
	Cyclizine	1	0	Advised to avoid, however, there is no evidence of teratogenicity (appropriate for patient's presentation)	✓
	Lidocaine	1	0	Use if benefits outweigh risks; not known to be harmful in animal studies	✓
	Metronidazole	1	1	Use only if potential benefit outweighs risk, avoid high-dose regimens	✓
Breastfeeding (n=7)	Azithromycin	1	1	Present in milk, use only if no suitable alternatives	✓
	Ceftriaxone	1	0	Compatible with breastfeeding; present in milk in low levels, but limited effects to infant	✓
	Cerazette®	1	0	Does not affect lactation	✓
	Depo Provera®	1	0	Present in milk, no adverse effects reported. First dose should be delayed until 6 weeks post-partum	✓
	Lidocaine	2	2	Present in milk but amount too small to be harmful	✓
	Metronidazole	1	0	Significant amount in milk, avoid large single doses, but otherwise compatible	✓
	Nexplanon	1	2	Does not affect lactation	✓
Renal/ kidney** (n=5)	Aciclovir	1	0	Use normal oral dose every 12 hours if eGFR less than 10 mL/minute/1.73 m^2**	✓
	Azithromycin & ceft.	0	1	Use in reduced dose if eGFR less than 10 mL/minute/1.73m^2**	✓
	Cryotherapy	1	0	No data in British National Formulary	✓
	Doxycycline	0	1	Use with caution, avoid excessive doses	✓
	Hepatitis B vaccine	0	1	No data in British National Formulary	✓
	Instillagel®	1	0	No data in British National Formulary	✓
	Lidocaine	0	1	Use with caution in severe renal impairment	✓
	Podophyllotoxin	1	0	No data in British National Formulary	✓
Liver (n=1)	Aqueous cream	0	1	No data in British National Formulary	✓

**patients may have received multiple drugs. INP= independent nurse prescribing, PGD= patient group directions, med= medication given, no med= no medication given, eGFR= estimated glomerular filtration rate, Ceft.= ceftriaxone. **no patient presented with acute or chronic renal failure. These conditions relate to kidney infections where eGFR was not considered to be impaired.*

Appendix GG. Specific medication available through PGDs by site

PGD medications active during study	Site 1	Site 2	Site 3	Site 4	Site 5
Anti-infective					
Aciclovir					
Azithromycin					
Cefixime					
Ceftriaxone (& lidocaine)	x2*	x2*			
Ciprofloxacin					
Clotrimazole (cream & pessary)		x2*	x2*	x2*	
Co-trimoxazole					
Doxycycline					
Fluconazole					
Hepatitis A vaccine				x2*	
Hepatitis B vaccine					
Imiquimod					
Liquid nitrogen					
Malathion					
Metronidazole	x2*				
Paracetamol					
Podophyllotoxin					
Trichloracetic acid					
Twinrix (Hepatitis A&B)					
Contraception					
Cerazette®, Cerelle® or Zelleta ®					
Cilest®					
Depo-Provera®					
Depo-Provera® (sub-cutaneous)					
Femodene ED®					
Femodene®, Katya 30/75® or Millinette 30/75®					
Femulen®					
Levonorgesterel					
Lidocaine 1% for contraceptive implants					
Loestrin 20®					
Loestrin 30®					
Logynon®					
Logynon ED ®					
Marvelon® or Gedarel® 30/150					
Mercilon® or Gedarel 20/150®					
Microgynon 30 ED®					
Microgynon®, Ovranette®, Levest® or Rigevidon®					
Micronor® or Noriday®					
Nexplanon®					
Norgeston®					

PGD medications active during study	Site 1	Site 2	Site 3	Site 4	Site 5
Norimin®					
Norinyl-1®					
Ovysmen®					
TriNovum®					
Ulipristal acetate					
Total	**20 (+2)**	**11 (+2)**	**12 (+1)**	**22 (+2)**	**37**

PGD added after the study

**x2 – demonstrates different medication preparations in separate PGD documents (e.g. clotrimazole topical cream and clotrimazole vaginal pessary). PGD = patient group direction*

Mean number of PGDs= 20.4 (SD: 10.4)

Range= 11 to 37 PGDs

Appendix HH. Clinical notes review: Detailed rationales for not being safe and/ or appropriate practice

Section		Rationale	INP		PGD		Total
			Med	No Med	Med	No Med	
Appropriate	Inappropriate	Unclear treatment rationale	1		2		3
		Incorrect treatment/ results given	1				1
		PEPSE indicated but not offered/ documented		1			1
		Combined oral contraceptive pill given with UKMEC 3			1		1
		PGD user signed medicine, but drug administered by another nurse			1		1
		Potential drug-drug interaction			1		1
		Symptomatic gonorrhoea contact not treated				1	1
	Intermediate	Further investigation of symptoms indicated	6	5	7	4	22
		Lack of documentation	3	6	10	1	20
		Error in 'prescription' documentation	2		5		7
		Pregnancy risk unclear	3	1	1		5
		Condition not treated	1		4		5
		Indicated medication not offered		1		4	5
		Medication not indicated	1		1		2
		Medication advice not accurate	1				1
	Not known	Limited summary of TOP attendance	26		8		34
		Lack of documentation		1	4	1	6
Safety	Unsafe	Incorrect treatment/ results given	1				1
		COCP given on UKMEC 3			1		1
		Potential drug-drug interaction			1		1
		Samples mixed up (investigated and resolved)		1			1
		PEPSE indicated but not offered/ documented		1			1
		Symptomatic gonorrhoea contact not treated				1	1
	Intermediate	Lack of documentation	11	1	20	1	33
		Potential drug-condition/ allergy interaction	3				3
		Further investigation of symptoms indicated	1		2	1	4
	Not known	Limited summary of TOP attendance	26		8		34
		Lack of documentation		1	1	1	3
Overall	Not safe/ appropriate	Incorrect treatment/ results given	1				1
		Combined oral contraceptive pill given with UKMEC 3			1		1
		Samples mixed up (investigated and resolved)		1			1
		PEPSE indicated but not offered/ documented		1			1
		Potential drug-drug interaction			1		1
		PGD user signed medicine, but administered by another nurse			1		1

Section		Rationale	INP		PGD		Total
			Med	No Med	Med	No Med	
		Symptomatic gonorrhoea contact not treated				1	1
	Undetermined	Limited summary of TOP attendance	26		8		34
		Lack of documentation	8	2	17	0	27
		Further assessment of symptoms indicated	2	1	3	4	10
		Unclear pregnancy risk assessment	3		2	2	7
		Condition not treated	1		4	1	6
PGD use		Medication clinically indicated and safe, but out with PGD restrictions			63		63

INP= independent nurse prescribing, PGD= patient group directions, med= medication given, no med= no medication given; PEPSE = post exposure prophylaxis for sexual exposure; UKMEC= UK medical eligibility criteria [3=risks outweigh the benefits of specific contraception method]; TOP= termination of pregnancy, COCP = combined oral contraceptive pill

Appendix II. Clinical notes review: Example of researcher and pharmacist review of potential medication interactions

Double/ Random Check	Drug prescribed	Documented PMH/ medications/ allergy	Interactions with PMH & Allergies or medications (between those prescribed on day and/ or concurrent)	Pharmacist's comments
Double	Metronidazole 400mg BD for 7/7 (PO assumed)	PMH: Asthma, Acne, Pregnant (requesting termination of pregnancy) Meds: Tetracycline Allergy: Penicillin	Pregnancy: manufacturer advises avoidance of high-dose regimens; use only if potential benefit outweighs risk. Risk of using tetracycline while pregnant (concurrent medication)	1) Taking into account the social picture of this patient's case (TOP), the decision of the choice of medication should lie with the clinician and patient to prescribe and take the medication that would otherwise be avoided in pregnancy. 2) For information, according to the [local] antibiotic app (Antibiotics in pregnancy and breastfeeding section) - ideally Penicillin or cephalosporin should be used first line but in the case of this patient due to her allergy status this would not be possible. Metronidazole is compatible in the first, second, third trimester and while breastfeeding. Tetracycline should be avoided in pregnancy (especially contraindicated in the second and third trimester - use with caution in the first - it should only be used if there are no other treatment options and administration cannot be delayed due to risk of infection to the mother
Random	Aciclovir 400mg PO TDS for 5/7	PMH: Nil Meds: Azithroymcin (4/7 earlier) & Warticon Allergy: Penicillin	No contraindications or cautions noted	Agreed
Random	Nexplanon 68mg SC implant stat& Lidocaine 1% as directed	PMH: Eating disorder & low bmi (13.1) Meds: Diazepam, Melatonin, Lansoprazole Allergy: Nil	No contraindications or cautions noted	Agreed
Random	Aciclovir 400mg PO BD for 4/12	PMH: Type 2 Diabetes, Lichen schlerosis Meds: Statins Allergy: Nil	No contraindications or cautions noted	Agreed
Random	Alprostadil (Caverjet 20mcg x4)	PMH: HIV Meds: Truvada, Darunavir, Ritonavir Allergy: Nil	No contraindications or cautions noted	No information found regarding interaction with ARVs stated
Random	Ceftriaxone 500mg IM stat, lidocaine 1% (as dilutent) & azithromycin 1G PO STAT	PMH: HIV Meds: ARV's Allergy: Nil	No contraindications or cautions noted	No ARVs stated - unable to check for interactions

PMH: past medical history, Meds: concurrent medications, ARV's: anti-retro viral medication

Appendix JJ. Observational study: Consultation content

INP/ PGD	Attendance type	Procedure/ diagnosis	Medication delivered	Face-to-face time (mins*)
INP 1	New	Maintain contraception (OCP) [asymptomatic screen]	Microgynon	25
INP 2	New	Change contraception (IUD to oral pill)	Microgynon	24
INP 3	New	Maintain contraception & genital warts	Depo Provera; Warticon Cream	25
INP 4	Follow-up	Hepatitis B vaccination	Twinrix (hepatitis A&B vaccine)	15
INP 5	Follow-up	Chlamydia (urethral & rectal); vaccine	Doxycycline; Hepatitis B vaccine	30
INP 6	New	New contraception (OCP) to avoid bleeding on implant	Microgynon	18
INP 7	Follow-up	Syphilis (primary)	Benzathine	22
INP 8	New	Maintain contraception (implant)	Nexplanon & lidocaine	44**
INP 9	New	Change contraception (patch to implant)	Nexplanon & lidocaine	24
INP 10	New	Syphilis contact	Benzathine	17
INP 11	Follow-up	Gonorrhoea (rectal) & chlamydia (rectal)	Ceftriaxone, lidocaine & azithromycin; doxycycline	20
INP 12	New	Human papilloma virus vaccine	Gardasil	13
INP 13	Follow-up	Chlamydia	Azithromycin	5**
INP 14	Follow-up	Chlamydia (rectal) & Equivical gonorrhoea (throat)	Doxycycline; spectinomycin & azithromycin	15
INP 15	Follow-up	Chlamydia & vulval-vaginal candidosis (prophalaxsis)	Azithromycin; clotrimazole cream & pessary	11
PGD 1	New	Change contraception (IUD to diaphram)	Diaphram	11
PGD 2	New	Change contraception (IUD to oral pill)	Cerelle	35
PGD 3	Follow-up	Chlamydia	Doxycycline	18
PGD 4	New	Maintain contraception (implant)	Nexplanon & lidocaine	23
PGD 5	New	New contraception (OCP)	Microgynon (everyday)	27
PGD 6	New	Maintain contraception (OCP)	Microgynon	12
PGD 7	Follow-up	Chlamydia	Azithromycin	13
PGD 8	Follow-up	Bacterial vaginosis & vulvo-vaginal candidosis	Metronidazole; clotrimazole cream & pessary	8**
PGD 9	Follow-up	Chlamydia	Azithromycin	7

INP/ PGD	Attendance type	Procedure/ diagnosis	Medication delivered	Face-to-face time (mins*)
PGD 10	New	Gonorrhoea	Ceftriaxone, lidocaine & azithromycin	15
PGD 11	Follow-up	Chlamydia (rectal)	Doxycycline	10
PGD 12	New	Change contraception (OCP to OCP)	Cilest	25
PGD 13	Follow-up	Chlamydia/ epipidymitis	Doxycycline (INP prescription)	27
PGD 14	New	Maintain contraception (POP)	Zelleta	8
PGD 15	New	Chlamydia contact	Azithromycin	15

** time is rounded up to nearest minute. Time refers to time nurses were known to spend face-to-face with patients, not duration of audio-recordings*
***additional support provided from a professional colleagues (time stated does not include the colleagues' time)*
INP =independent nurse prescribing, PGD= patient group directions, OCP = oral contraceptive pill, POP = progesterone only pill, IUD – intrauterine devices

Appendix KK. Observational study: Detailed Prescribing Framework scoring of observations

Prescribing Framework (RPS, 2016): Competency 1: ASSESS THE PATIENT	INP						PGD					
	Observed		Not observed		Not applicable		Observed		Not observed		Not applicable	
	n	%	n	%	n	%	n	%	n	%	n	%
1.1 Takes an appropriate medical, social and medication history, including allergies and intolerances.	15	100	0	0.0	0	0.0	15	100	0	0.0	0	0.0
1.2 Undertakes an appropriate clinical assessment.	15	100	0	0.0	0	0.0	15	100	0	0.0	0	0.0
1.3 Accesses and interprets all available and relevant patient records to ensure knowledge of the patient's management to date.	15	100	0	0.0	0	0.0	15	100	0	0.0	0	0.0
1.4 Requests and interprets relevant investigations necessary to inform treatment options.	12	80	0	0.0	3	20.0	13	86.7	0	0.0	2	13.3
1.5 Makes, confirms or understands, the working or final diagnosis by systematically considering the various possibilities	15	100	0	0.0	0	0.0	15	100	0	0.0	0	0.0
1.6 Understands the condition(s) being treated, their natural progression and how to assess their severity, deterioration and anticipated response to treatment.	15	100	0	0.0	0	0.0	15	100	0	0.0	0	0.0
1.7 Reviews adherence to and effectiveness of current medicines.	7	46.7	1	6.7	7	46.7	6	40.0	0	0.0	9	60
1.8 Refers to or seeks guidance from another member of the team, a specialist or a prescribing information source when necessary.	2	13.3	0	0.0	13	86.7	5	33.3	0	0.0	10	66.7

INP =independent nurse prescribing, PGD= patient group directions, RPS = Royal Pharmaceutical Society

Prescribing Framework (RPS, 2016): Competency 2: CONSIDER THE OPTIONS	INP								PGD							
	Observed		Implied practice		Not observed		Not applicable		Observed		Implied practice		Not observed		Not applicable	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
2.1 Considers both non-pharmacological (including no treatment) and pharmacological approaches to modifying disease and promoting health.	0	0.0	0	0.0	0	0.0	15	100	0	0.0	0	0.0	0	0.0	15	100
2.2 Considers all pharmacological treatment options including optimising doses as well as stopping treatment (appropriate polypharmacy, de-prescribing).	14	93.3	0	0.0	0	0.0	1	6.7	14	93.3	1	6.7	0	0.0	0	0.0
2.3 Assesses the risks and benefits to the patient of taking or not taking a medicine or treatment.	15	100	0	0.0	0	0.0	0	0.0	15	100	0	0.0	0	0.0	0	0.0
2.4 Applies understanding of the mode of action and pharmacokinetics of medicines and how these may be altered (e.g. by genetics, age, renal impairment, pregnancy).	4	26.7	11	73.3	0	0.0	0	0.0	7	46.7	8	53.3	0	0.0	0	0.0
2.5 Assesses how co-morbidities, existing medication, allergies, contraindications and quality of life impact on management options.	15	100	0	0.0	0	0.0	0	0.0	14	93.3	0	0.0	0	0.0	1	6.7
2.6 Takes into account any relevant patient factors (e.g. ability to swallow, religion) and the potential impact on route of administration and formulation of medicines.	8	53.3	6	40.0	1	6.7	0	0.0	5	33.3	10	66.7	0	0.0	0	0.0
2.7 Identifies, accesses, and uses reliable and validated sources of information and critically evaluates other information.	0	0.0	15	100	0	0.0	0	0.0	1	6.7	14	93.3	0	0.0	0	0.0
2.8 Stays up-to-date in own area of practice and applies the principles of evidence-based practice, including clinical and cost-effectiveness.	0	0.0	15	100	0	0.0	0	0.0	0	0.0	15	100	0	0.0	0	0.0

Prescribing Framework (RPS, 2016): Competency 2: CONSIDER THE OPTIONS	INP								PGD							
	Observed		Implied practice		Not observed		Not applicable		Observed		Implied practice		Not observed		Not applicable	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
2.9 Takes into account the wider perspective including the public health issues related to medicines and their use and promoting health.	12	80.0	3	20.0	0	0.0	0	0.0	14	93.3	1	6.7	0	0.0	0	0.0
2.10 Understands antimicrobial resistance and the roles of infection prevention, control and antimicrobial stewardship measures.	0	0.0	7	46.7	0	0.0	8	53.3	2	13.3	6	40.0	0	0.0	7	46.7

INP =independent nurse prescribing, PGD= patient group directions, RPS = Royal Pharmaceutical Society

Prescribing Framework (RPS, 2016): Competency 3: REACH A SHARDED DECISION	INP						PGD					
	Observed		Not observed		Not applicable		Observed		Not observed		Not applicable	
	n	%	n	%	n	%	n	%	n	%	n	%
3.1 Works with the patient/carer in partnership to make informed choices, agreeing a plan that respects patient preferences including their right to refuse or limit treatment.	15	100	0	0.0	0	0.0	15	100	0	0.0	0	0.0
3.2 Identifies and respects the patient in relation to diversity, values, beliefs and expectations about their health and treatment with medicines.	15	100	0	0.0	0	0.0	15	100	0	0.0	0	0.0
3.3 Explains the rationale behind and the potential risks and benefits of management options in a way the patient/carer understands.	15	100	0	0.0	0	0.0	15	100	0	0.0	0	0.0
3.4 Routinely assesses adherence in a non-judgemental way and understands the different reasons non-adherence can occur (intentional or non-intentional) and how best to support patients/carers.	12	80.0	0	0.0	3	20.0	15	100	0	0.0	0	0.0
3.5 Builds a relationship which encourages appropriate prescribing and not the expectation that a prescription will be supplied.	15	100	0	0.0	0	0.0	15	100	0	0.0	0	0.0
3.6 Explores the patient/carers understanding of a consultation and aims for a satisfactory outcome for the patient/carer and prescriber.	15	100	0	0.0	0	0.0	15	100	0	0.0	0	0.0

INP =independent nurse prescribing, PGD= patient group directions, RPS = Royal Pharmaceutical Society

Prescribing Framework (RPS, 2016): Competency 4: PRESCRIBE	INP								PGD							
	Observed		Implied practice		Not observed		Not applicable		Observed		Implied practice		Not observed		Not applicable	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
4.1 Prescribes a medicine only with adequate, up-to-date awareness of its actions, indications, dose, contraindications, interactions, cautions, and side effects.	6	40.0	9	60.0	0	0.0	0	0.0	7	46.7	8	53.3	0	0.0	0	0.0
4.2 Understands the potential for adverse effects and takes steps to avoid/minimise, recognise and manage them.	14	93.3	0	0.0	1	6.7	0	0.0	15	100	0	0.0	0	0.0	0	0.0
4.3 Prescribes within relevant frameworks for medicines use as appropriate (e.g. local formularies, care pathways, protocols and guidelines).	15	100	0	0.0	0	0.0	0	0.0	14	93.3	1	6.7	0	0.0	0	0.0
4.4 Prescribes generic medicines where practical and safe for the patient and knows when medicines should be prescribed by branded product.	15	100	0	0.0	0	0.0	0	0.0	15	100	0	0.0	0	0.0	0	0.0
4.5 Understands and applies relevant national frameworks for medicines use (e.g. NICE, SMC, AWMSG and medicines management/optimisation) to own prescribing practice.	0	0.0	15	100	0	0.0	0	0.0	1	6.7	14	93.3	0	0.0	0	0.0
4.6 Accurately completes and routinely checks calculations relevant to prescribing and practical dosing.	2	13.3	2	13.3	0	0.0	11	73.3	1	6.7	0	0.0	0	0.0	14	93.3
4.7 Considers the potential for misuse of medicines.	0	0.0	0	0.0	0	0.0	15	100	0	0.0	0	0.0	0	0.0	15	100
4.8 Uses up-to-date information about prescribed medicines (e.g. availability, pack sizes, storage conditions, excipients, costs).	0	0.0	15	100	0	0.0	0	0.0	2	13.3	13	86.7	0	0.0	0	0.0
4.9 Electronically generates or writes legible unambiguous and complete prescriptions which meet legal requirements.	14	93.3	0	0.0	1	6.7	0	0.0	15	100	0	0.0	0	0.0	0	0.0

Prescribing Framework (RPS, 2016): Competency 4: PRESCRIBE	INP								PGD							
	Observed		Implied practice		Not observed		Not applicable		Observed		Implied practice		Not observed		Not applicable	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
4.10 Effectively uses the systems necessary to prescribe medicines (e.g. medicine charts, electronic prescribing, decision support).	14	93.3	0	0.0	1	6.7	0	0.0	15	100	0	0.0	0	0.0	0	0.0
4.11 Only prescribes medicines that are unlicensed, 'off-label', or outside standard practice if satisfied that an alternative licensed medicine would not meet the patient's clinical needs.	4	26.7	0	0.0	0	0.0	11	73.3	1	6.7	0	0.0	0	0.0	14	93.3
4.12 Makes accurate legible and contemporaneous records and clinical notes of prescribing decisions.	13	86.7	0	0.0	2	13.3	0	0.0	15	100	0	0.0	0	0.0	0	0.0
4.13 Communicates information about medicines and what they are being used for when sharing or transferring prescribing responsibilities/ information.	13	86.7	0	0.0	1	6.7	1	6.7	15	100	0	0.0	0	0.0	0	0.0

INP =independent nurse prescribing, PGD= patient group directions, RPS = Royal Pharmaceutical Society

Prescribing Framework (RPS, 2016): Competency 5: PROVIDE INFORMATION	INP						PGD					
	Observed		Not observed		Not applicable		Observed		Not observed		Not applicable	
	n	%	n	%	n	%	n	%	n	%	n	%
5.1 Checks the patient/carer's understanding of and commitment to the patient's management, monitoring and follow-up.	15	100	0	0.0	0	0.0	14	93.3	0	0.0	1	6.7
5.2 Gives the patient/carer clear, understandable and accessible information about their medicines (e.g. what it is for, how to use it, possible unwanted effects and how to report them, expected duration of treatment).	15	100	0	0.0	0	0.0	15	100	0	0.0	0	0.0
5.3 Guides patients/carers on how to identify reliable sources of information about their medicines and treatments.	10	66.7	5	33.3	0	0.0	13	86.7	2	13.3	0	0.0
5.4 Ensures that the patient/carer knows what to do if there are any concerns about the management of their condition, if the condition deteriorates or if there is no improvement in a specific time frame.	12	80.0	3	20.0	0	0.0	13	86.7	2	13.3	0	0.0
5.5 When possible, encourages and supports patients/carers to take responsibility for their medicines and self-manage their conditions.	10	66.7	0	0.0	5	33.3	15	100	0	0.0	0	0.0

INP =independent nurse prescribing, PGD= patient group directions, RPS = Royal Pharmaceutical Society

Prescribing Framework (RPS, 2016): Competency 6: MONITOR AND REVIEW	INP						PGD					
	Observed		Not observed		Not applicable		Observed		Not observed		Not applicable	
	n	%	n	%	n	%	n	%	n	%	n	%
6.1 Establishes and maintains a plan for reviewing the patient's treatment.	12	80.0	0	0.0	3	20.0	14	93.3	0	0.0	1	6.7
6.2 Ensures that the effectiveness of treatment and potential unwanted effects are monitored.	15	100	0	0.0	0	0.0	15	100	0	0.0	0	0.0
6.3 Detects and reports suspected adverse drug reactions using appropriate reporting systems.	0	0.0	0	0.0	15	100	0	0.0	0	0.0	15	100
6.4 Adapts the management plan in response to on-going monitoring and review of the patient's condition and preferences.	12	80.0	0	0.0	3	20.0	12	80.0	0	0.0	3	20.0

INP =independent nurse prescribing, PGD= patient group directions, RPS = Royal Pharmaceutical Society

Appendix LL. Patient questionnaire: Satisfaction with Information about Medicines Scale (SIMS) scores

Satisfaction with Information about Medicines Scale (SIMS)		INP (n=174)		PGD (n=169)		Not known(n=5)		Total (n=348)	
		n	%	n	%	n	%	n	%
1. The name of the medicine	Too much	10	5.7	8	4.7	0	0.0	18	5.2
	About right	152	87.4	151	89.3	5	100.0	308	88.5
	Too little	2	1.1	1	0.6	0	0.0	3	0.9
	None received	5	2.9	2	1.2	0	0.0	7	2.0
	Not applicable	5	2.9	7	4.1	0	0.0	12	3.4
	Missed	0	0.0	0	0.0	0	0.0	0	0.0
2.What your medicine is for	Too much	15	8.6	12	7.1	0	0.0	27	7.8
	About right	153	87.9	153	90.5	5	100.0	311	89.4
	Too little	0	0.0	0	0.0	0	0.0	0	0.0
	None received	0	0.0	0	0.0	0	0.0	0	0.0
	Not applicable	4	2.3	3	1.8	0	0.0	7	2.0
	Missed	2	1.1	1	0.6	0	0.0	3	0.9
3. What it does	Too much	17	9.8	14	8.3	0	0.0	31	8.9
	About right	149	85.6	149	88.2	4	80.0	302	86.8
	Too little	2	1.1	2	1.2	1	20.0	5	1.4
	None received	2	1.1	2	1.2	0	0.0	4	1.1
	Not applicable	3	1.7	2	1.2	0	0.0	5	1.4
	Missed	1	0.6	0	0.0	0	0.0	1	0.3
4. How it works	Too much	18	10.3	11	6.5	0	0.0	29	8.3
	About right	138	79.3	142	84.0	3	60.0	283	81.3
	Too little	7	4.0	3	1.8	2	40.0	12	3.4
	None received	7	4.0	8	4.7	0	0.0	15	4.3
	Not applicable	3	1.7	3	1.8	0	0.0	6	1.7
	Missed	1	0.6	2	1.2	0	0.0	3	0.9
5. How long it will take to act	Too much	19	10.9	12	7.1	0	0.0	31	8.9
	About right	146	83.9	143	84.6	4	80.0	293	84.2
	Too little	5	2.9	5	3.0	1	20.0	11	3.2
	None received	0	0.0	4	2.4	0	0.0	4	1.1
	Not applicable	3	1.7	5	3.0	0	0.0	8	2.3
	Missed	1	0.6	0	0.0	0	0.0	1	0.3
6. How can you tell if it's working	Too much	13	7.5	10	5.9	0	0.0	23	6.6
	About right	131	75.3	121	71.6	4	80.0	256	73.6
	Too little	6	3.4	8	4.7	1	20.0	15	4.3
	None received	10	5.7	13	7.7	0	0.0	23	6.6
	Not applicable	13	7.5	17	10.1	0	0.0	30	8.6
	Missed	1	0.6	0	0.0	0	0.0	1	0.3
7. How long you will need to be on your medicine	Too much	16	9.2	15	8.9	0	0.0	31	8.9
	About right	144	82.8	136	80.5	5	100.0	285	81.9
	Too little	0	0.0	0	0.0	0	0.0	0	0.0
	None received	1	0.6	1	0.6	0	0.0	2	0.6

Satisfaction with Information about Medicines Scale (SIMS)		INP (n=174)		PGD (n=169)		Not known(n=5)		Total (n=348)	
		n	%	n	%	n	%	n	%
	Not applicable	12	6.9	14	8.3	0	0.0	26	7.5
	Missed	3	1.7	2	1.2	0	0.0	5	1.4
8. How to get a further supply	Too much	15	8.6	11	6.5	0	0.0	26	7.5
	About right	112	64.4	117	69.2	3	60.0	232	66.7
	Too little	5	2.9	2	1.2	0	0.0	7	2.0
	None received	10	5.7	4	2.4	2	40.0	16	4.6
	Not applicable	28	16.1	33	19.5	0	0.0	61	17.5
	Missed	4	2.3	2	1.2	0	0.0	6	1.7
9. Whether the medicine has any unwanted side effects	Too much	15	8.6	12	7.1	0	0.0	27	7.8
	About right	136	78.2	131	77.5	3	60.0	270	77.6
	Too little	1	0.6	5	3.0	0	0.0	6	1.7
	None received	13	7.5	10	5.9	2	40.0	25	7.2
	Not applicable	8	4.6	10	5.9	0	0.0	18	5.2
	Missed	1	0.6	1	0.6	0	0.0	2	0.6
10. What are the risks of getting side effects	Too much	14	8.0	13	7.7	0	0.0	27	7.8
	About right	137	78.7	124	73.4	3	60.0	264	75.9
	Too little	1	0.6	6	3.6	0	0.0	7	2.0
	None received	17	9.8	9	5.3	2	40.0	28	8.0
	Not applicable	4	2.3	14	8.3	0	0.0	18	5.2
	Missed	1	0.6	3	1.8	0	0.0	4	1.1
11. What you should do if you experience unwanted side effects	Too much	13	7.5	12	7.1	0	0.0	25	7.2
	About right	127	73.0	121	71.6	3	60.0	251	72.1
	Too little	4	2.3	4	2.4	0	0.0	8	2.3
	None received	17	9.8	18	10.7	2	40.0	37	10.6
	Not applicable	12	6.9	13	7.7	0	0.0	25	7.2
	Missed	1	0.6	1	0.6	0	0.0	2	0.6
12. Whether you can drink alcohol whilst taking the medicine	Too much	11	6.3	13	7.7	0	0.0	24	6.9
	About right	94	54.0	89	52.7	3	60.0	186	53.4
	Too little	7	4.0	3	1.8	0	0.0	10	2.9
	None received	27	15.5	29	17.2	2	40.0	58	16.7
	Not applicable	32	18.4	33	19.5	0	0.0	65	18.7
	Missed	2	1.1	2	1.2	0	0.0	4	1.1
13. Whether the medicine interferes with other medicines you are currently taking	Too much	10	5.7	9	5.3	0	0.0	19	5.5
	About right	117	67.2	109	64.5	4	80.0	230	66.1
	Too little	6	3.4	4	2.4	0	0.0	10	2.9
	None received	14	8.0	13	7.7	1	20.0	28	8.0
	Not applicable	23	13.2	32	18.9	0	0.0	55	15.8
	Missed	4	2.3	2	1.2	0	0.0	6	1.7
14. Whether the medication will make you feel drowsy	Too much	11	6.3	9	5.3	0	0.0	20	5.7
	About right	97	55.7	89	52.7	3	60.0	189	54.3
	Too little	5	2.9	6	3.6	0	0.0	11	3.2
	None received	25	14.4	27	16.0	2	40.0	54	15.5
	Not applicable	29	16.7	36	21.3	0	0.0	65	18.7
	Missed	7	4.0	2	1.2	0	0.0	9	2.6

Satisfaction with Information about Medicines Scale (SIMS)		INP (n=174)		PGD (n=169)		Not known(n=5)		Total (n=348)	
		n	%	n	%	n	%	n	%
15. Whether you were able to have sex while taking the medicine	Too much	16	9.2	16	9.5	0	0.0	32	9.2
	About right	133	76.4	126	74.6	4	80.0	263	75.6
	Too little	3	1.7	1	0.6	0	0.0	4	1.1
	None received	8	4.6	6	3.6	1	20.0	15	4.3
	Not applicable	14	8.0	18	10.7	0	0.0	32	9.2
	Missed	0	0.0	2	1.2	0	0.0	2	0.6
16. What to do if you forget to take a dose	Too much	10	5.7	10	5.9	0	0.0	20	5.7
	About right	96	55.2	86	50.9	3	60.0	185	53.2
	Too little	3	1.7	6	3.6	0	0.0	9	2.6
	None received	13	7.5	17	10.1	2	40.0	32	9.2
	Not applicable	48	27.6	45	26.6	0	0.0	93	26.7
	Missed	4	2.3	5	3.0	0	0.0	9	2.6

INP = independent nurse prescribing, PGD = patient group directions